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Exhibit 6

To: Distribution
From: Eric Peterson
Date: August 24, 1994
Subject: New Platform .014 RX/OTW Concept Review

Meeting Date: **Tuesday, August 30, 1994**
Time: **8:00 - 12:00**
Location: Training Room A, Santa Clara

Preliminary Agenda

Introduction	Ruth Fricker	8:00 - 8:05
Project Plan	Eric Peterson	8:05 - 8:20
Market Needs	Chris Haig	8:20 - 8:40
Technology Readiness	Eric Peterson	8:40 - 9:00
Product Design/Test Results	Dan Cox, Eric Leopold	9:00 - 10:15
Break		10:15 - 10:30
Potential Failure Modes	Victor Ngyen, Diem Ta	10:30 - 10:50
Manufacturing	Jonathon Lonczak, Kevin Britten	10:50 - 11:00
Project Schedule	Eric Peterson	11:00 - 11:15
Summary, Recommendations	Eric Peterson	11:15 - 11:30
Additional Q&A		11:30 - 12:00

New Platform Team

Bob Ainsworth	S127
Kevin Britton	T520
Robbin Cherry	S117
Dan Cox	S118
Mandy Lee	S243
Eric Leopold	S126
Steve Levin	S243
Johnathan Lonczak	T520
Minoo Mama	S243
Colleen McQueen	S123
Dan Meeker	S126
Victor Nguyen	S230
Eric Peterson	S127
Judi Palin	S125
Ron Sejna	S123
Barbara Stamberg	S107
Diem Ta	S106
Larry Wasicek	S120
Ruth Fricker	S124

Design Review Jury

Jessica Chiu	S127
Joann Heberer	S119
Don Swanston	T520

VP Reps

RA/QA - Ed Sinclair	S236
Mkt - Carrie Bates	S112
R&D - Peter McInnes	S122
Mfg - Susan Slane	T520

Invitees

Richard Allen	S240
Jon Becker	S116
Laura Crawford	T520
Tim Dietz	S115
Tom Douthitt	S112
Mike Kolber	S125
Lois Lonczak	T200
Olga Malito	S116
Keten Muni	S101
Vidya Nayak	S240
Sam Omaleki	S240
Dean Powelson	T520
Bob Saltman	S110
Gary Schneiderman	S125
Bill Winton	T500
Chris Yelley	T200
Margo Zaugg	S123

cc:

Ginger Howard	S212
Gary Johnson	S121

New Platform .014

Concept Review

August 30, 1994

Review Packet Contents

New Platform .014

Concept Review

August 30, 1994

Agenda

- Introduction
- Project Plan
- Market Needs Assessment
- Technology Readiness
- Product Design/Test Results to date
- Potential Failure Modes
- Manufacturing
- Project Schedule
- Summary, Recommendations

Project Information

- Project #1315
- Project Leader: Eric Peterson
- New Platform for global .014 workhorse OTW and RX catheters
- Catheters will introduce Soft Lo-Pro balloon technology
- Corporate Priority #12

Project Goals

- Performance
  - Best "overall" performance
- Cost
  - Stretch goal of 50% COPS reduction
  - COPS less than EDGE/Streak .014
  - Have a common distal end
- Timing Goals (with longs)
  - Q4 1995 International Release
  - Q2 1996 Domestic Release

Best "Overall" Performance

QFD Attribute	Critical Success Factors
glide through tortuous artery without resistance	best in class
Crosses difficult, distal lesions	competitive*
smooth movement between catheter and guidewire	best in class
transmit push from back end to distal tip	best in class
atraumatic tip	competitive
crosses second lesion after inflation	equal

* Performance goal has been "equal" cross, see recommendations

Synergy with Strategic Objectives

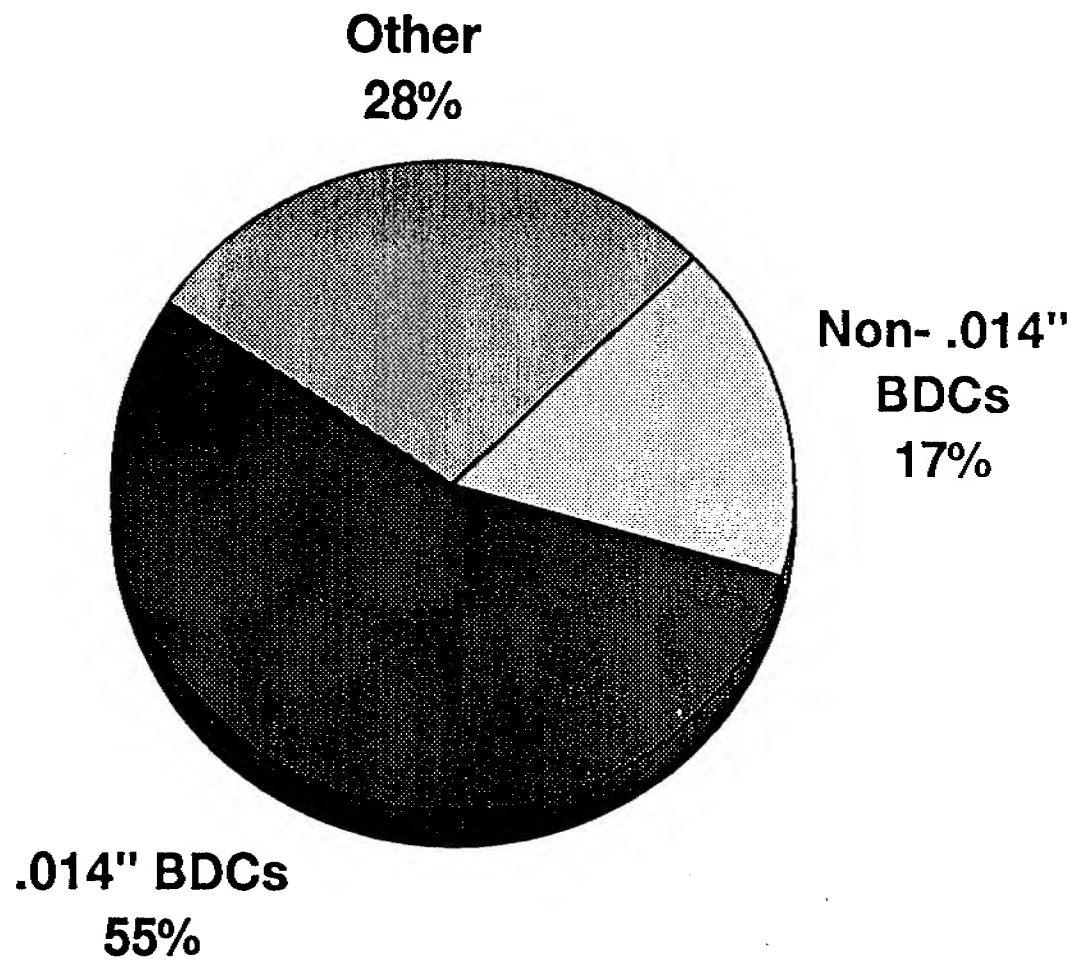
- Grow proprietary segments
  - continue to innovate in RX designs
- Increase share in OTW
  - deliver competitive OTW product
- Grow international presence
  - greater international input into design
- Increase productivity
  - common design features (distal end)
  - lower product COPS

New Platform Team Members

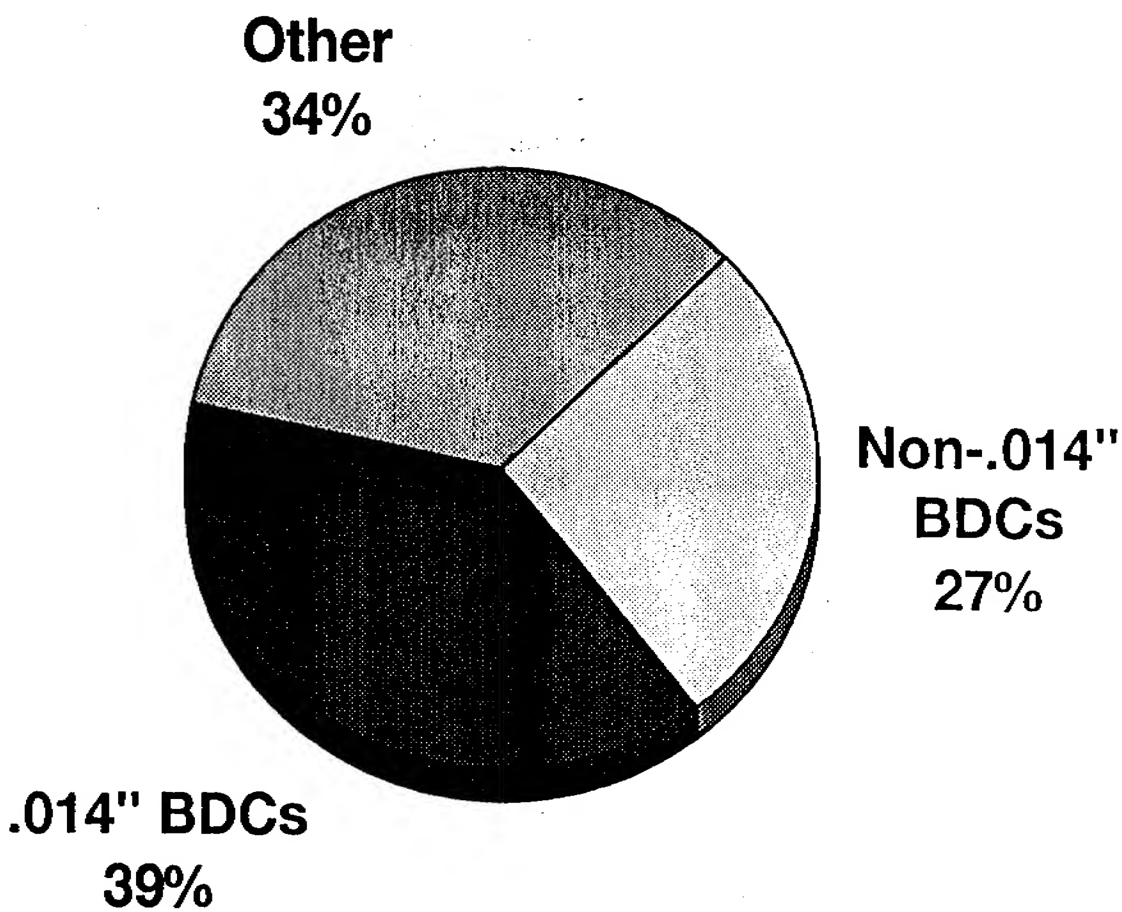
- Eric Peterson, Project Leader
- Dan Cox, OTW Tech. Lead
- Eric Leopold, RX Tech. Lead
- Larry Wasicek, R&D Engr.
- Bob Alcantara, R&D Tech
- Barbara Stamberg, R&D Tech
- Erick Abeleven, R&D Tech
- Robbin Cherry, R&D Tech
- Kim Nguyen, R&D Tech
- Chris Haig, Marketing
- Colleen McQueen, CR
- Ron Sejna, CR
- Dan Meeker, IR
- Judi Palin, RA
- Diem Ta, RE
- Victor Ngyuen, QE
- Jon Lonczak, ME
- Kevin Britton, ME
- Mandy Lee, Process
- Minoo Mama, Process
- Steven Levin, Process
- Bob Ainsworth, Shafts
- Lois Lonczak, Soft LoPro
- Tim Dietz, Soft LoPro
- Laura Crawford, Hydrophilic

MARKET NEEDS ASSESSMENT

1993 Total Worldwide PTCA Market: $1.1B

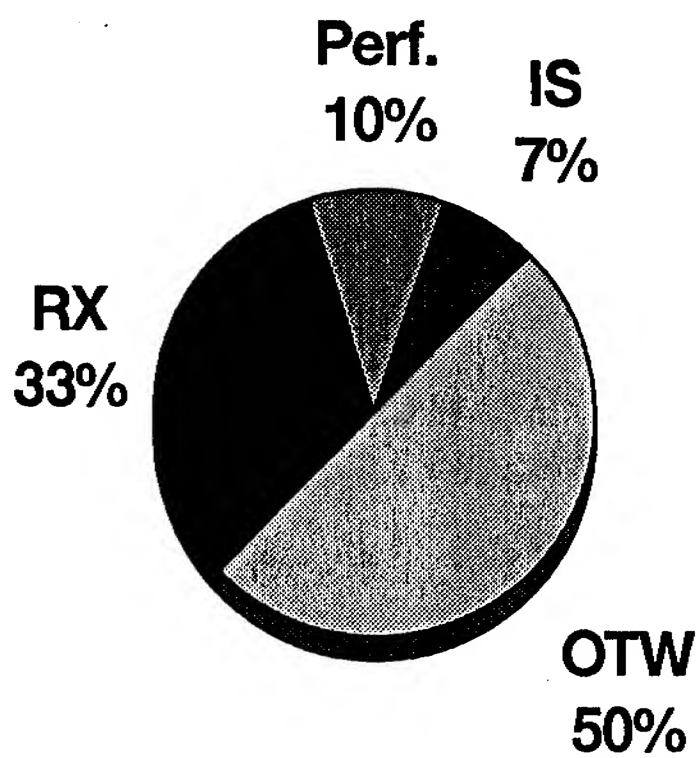


ACS Revenues 1993

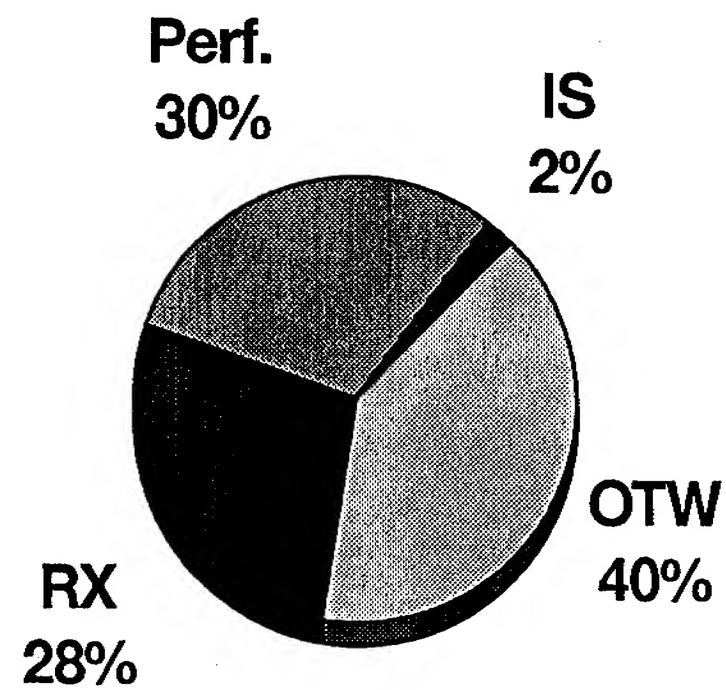


BDC Breakdown (units)

Total WW



ACS WW



Leading BDCs

	US		Germany		Japan	
	Product	Share	Product	Share	Product	Share
1	Elipse	12.3%	Express	13%	Edge	16%
2	Flowtrack	10.9%	Magical Speedy	9%	Sleek	10%
3	Cobra 14	9.5%	Gold Exchange	6%	Cobra	10%
4	RX Perf.	5.6%	14K	5%	14K	8%
5	14K	4.5%	Streak	5%	Agil	8%

Environmental Overview - U.S.

- World's largest market (400K procedures in 1993)
- OTW segment very competitive
- ACS has dominant share in RX
- Prices falling
- Full-line offering becoming more important

Environmental Overview - Germany

- Second largest market (procedures)
- Average price is higher than in U.S., but declining ASPs
- Primarily an RX market (65%)
- Many competitors in RX

Environmental Overview - Japan

- Primarily an OTW market (80%)
- Second largest market (~~units &~~ $)
- Relatively high growth rate for procedures
- High gov't. set reimbursement
- Consignment
- Many complex cases (aversion to CABG)

Competitive Overview

Scimed

- Expanding product offering
- Targeting Int'l expansion & OTW segment in U.S.
- Launch of Cobra Swift Tip, Dispatch
- Falling U.S. market share

Cordis

- Full-line offering
- Many new high quality products (Sleek, Europass)
- Increasing market share

Competitive Overview

<u>Medtronic</u>

- Broad range of cardiology products
- Angioplasty not main business, but ...
- Some good products (14K, Sherpa guides)

<u>Schneider</u>

- Strong in Europe, weak in U.S.
- Strong product pipeline
- Hopes to make gains in U.S. RX market

Current ACS Products
Customer Perception

	Edge	Elipse
Strengths	• Good overall performance • Reliable balloon material • Guide wire movement	• Innovative design • Good/exe. overall perf. • Track • Push • Reliable balloon material
Weaknesses	• Cross • Push • No high pressure	• Cross (compared to BIC) • No high pressure • Springy shaft

U.S. Customer Needs

1. **Slides through tortuous artery without resistance**
2. **Crosses difficult distal lesions**
3. **Smooth guide wire movement**
4. **Transmits push from back end to distal tip**
5. **Predictable balloon size during inflations**
6. **Atraumatic tip**
7. **Predictable balloon rupture pressure**
8. **Crosses second lesion after inflation**
9. Simple guide wire exchange
10. Simple balloon catheter exchange
11. Balloon catheter shaft doesn't kink during exchange
12. Good visualization during proximal injections
13. Balloon catheter doesn't cause guide wire (GW) to kink in anatomy
14. **Ability to dilate at higher pressures**
15. Balloon catheter doesn't cause GW to kink during exchange
16. Balloon doesn't straighten the artery
17. **Can use smaller guiding catheters**
18. Good inflation/deflation times
19. **Can achieve nominal balloon size at low pressure**
20. **Can use two balloon catheters in guiding catheter**
21. Easy to load GW
22. Minimize blood loss at RHV
23. Compatible with .018 GWs
24. Easy to flush GW lumen
25. Can be used in Angiographic catheters
26. Stores well on table

Best In Class

Attribute	BIC
Slides through tortuous artery without resistance	Sleek
Crosses difficult distal lesions	Sleek
Smooth guide wire movement	14K
Transmits push from back end to distal tip	CobraBio
Predictable balloon size during inflations	Edge
Atraumatic tip	Sleek
Predictable balloon rupture pressure	Elipse
Crosses second lesion after inflation	Sleek
Ability to dilate at higher pressures	Sleek
Can use smaller guiding catheters	Sleek
Can achieve nominal balloon size at low pressure	Elipse
Can use two balloon catheters in guiding catheter	Rally

Positioning
Best in Overall Performance

Attribute	Goal
Slides through tortuous artery without resistance	Best in class
Crosses difficult distal lesions	Competitive
Smooth guide wire movement	Best in class
Transmits push from back end to distal tip	Best in class
Atraumatic tip	Competitive
Crosses second lesion after inflation	Equal the competition
Ability to dilate at higher pressures	Competitive

Technologies

- Soft LoPro Balloon
- Hydrophilic Coating
- E-Beam Sterilization
- PEEK Stiff Shaft

Soft Lo Pro Balloon

- Goals
  - Higher burst pressure (10 atm RBP, 15 atm mean)
  - Lower Profile/improved cross
  - Softer balloon/improved recross
- Status
  - Concept Review held on 7/27/94. 3.0mm LoPro balloon with ETO sterilization met original project goals
  - Decision made to proceed with current blend on 8/12/94.
  - Preliminary feedback from E-Beam sterilization and hydrophilic evaluations shows no significant impact on balloon performance.
  - New "Neat" resin shows promise to eliminate compounding and reduce rupture and balloon OD standard deviations.

Soft Lo Pro continued ...

- Timeline/Milestones
  - 50/50 and "Neat" resin evaluation — 8/31/94
    - comparison of 2.0, 3.0, and 4.0 performance data and capability for both 50/50 blend and "neat" resin
  - Decision on resin for LoPro — 9/1/94
  - Hydrophilic/E-beam evaluation — 8/31/94
  - Processing/folding optimization — 10/94
  - Hydrophilic/E-beam qualification — 11/94
  - Design Review (3.0, 2.0, 4.0, 1.5) — 12/94
  - Remaining sizes and validation — Q1 1995

Soft Lo Pro continued ...

- Issues/Risks
  - 50/50 Blend - process optimization to reduce balloon OD and rupture standard deviations may not have a significant impact
  - "Neat" Resin - balloon performance testing is underway and only preliminary results are available

Hydrophilic/E-Beam

- Goals
  - Improve track, cross, and recross by providing a significantly more lubricous coating than Microglide
- Status
  - Current project focus is on PE-600 Edge and Elipse
  - Have demonstrated the following performance:
    - 70% less force to cross than microglide
    - improvement over microglide in recross during animal studies
    - preliminary work shows 50% lower crossing force than Bioslide
  - New STM under development for wet profile measurement, data in Sept.

Hydrophilic/E-Beam continued...

- Timeline - PE600 Implementation
  - Edge filing — 11/30/94
  - EDC clinicals — Dec 94/Jan 95
  - Elipse filing — Jan/Feb 95
  - Edge Int'l release — Jan/Feb 95
  - Edge Dom. release — June 95

Hydrophilic/E-Beam continued...

- Issues/Risks
  - E-beam Sterilization
    - Data from heat set study due mid-Sept.
    - Will determine need for reengineering balloons after heat set study
  - Incorporate PAT II process
  - Merging of Low Cost & Hydrophilic
  - Potential Low Cost IM color change

PEEK Stiff Shaft

- Goals
  - High Stiffness, Good Kink Resistance
  - Low Cost, Easy Assembly into Catheter
- Status
  - PEEK tubing has highest stiffness of extrudable polymer resins
  - Acutech PEEK tubing has been used in current catheter prototyping
  - In-house extrusion process DOE demonstrated our ability to meet goals for extrusion properties.

PEEK Stiff Shaft continued...

- Timeline/Milestones
  - Secure PEEK resin supply, 11/1/94
  - Determine final shaft dimensions, 10/10/94
  - Optimize in-house extrusion process, 11/1/94
- Issues/Risks
  - Resin Supply
    - Victrex Inc.
    - AMOCO
  - Extrusion Source
    - In-house processing
    - Acutech Corp.

Performance / Design Goals

Attribute	Design Goal
Track	Better than Sleek / Europass
Cross	Competitive with Sleek / Europass
GW Movement	Equal to Edge / Better than Elipse
Push	Equal to Cobra / Elipse
Atraumatic Tip	Competitive with Sleek / Europass
Recross	Equal to Sleek / Europass
COPS	Improved over Edge / Elipse

Performance / Design Goals

Attribute	Design Goal
Tip Profile	≤ .030"
Balloon Profile	≤ .039"
Distal Shaft Size	≤ 2.7F
Proximal Shaft Size	≤ 3.1F(OTW) ≤ 2.8F(RX)
Relation to GC	1 catheter in a 6 F GC 1 catheter / 2 wires in a 7 F GC (RX)
Deflation Time	≤ 8 seconds for 3.0 x 20 ≤ 20 seconds for 4.0 x 40
Shaft Length	135 cm
Exchange Length	25 cm (RX)

Completed Design Decisions

- Elimination of peel away on the RX product
- Common distal shaft for RX and OTW catheters
- Soft LoPro balloon material
- PEEK or PEK proximal shaft material for OTW
- Reinforced single lumen design for RX proximal shaft
- PE based inner member for RX and OTW catheters
- Aggressive tip sanding method
- Coaxial distal shaft design

OTW Product Features to Address Customer Needs

Customer Need	Product Features
Slides through tortuous artery without resistance	Small distal shaft size Hydrophilic coating Soft LoPro Balloon
Crosses difficult distal lesions	Aggressive tip sand Soft LoPro balloon Hydrophilic coating PEEK proximal shaft
Smooth guide wire movement	Graphite/HDPE extended mandrel IM
Transmits push from back end to distal tip	PEEK proximal shaft PEEK/PE shaft junction Graphite/HDPE extended mandrel IM

OTW Product Features to Address Customer Needs

Customer Need	Product Features
Atraumatic tip	Aggressive tip sand Small tip diameter Soft LoPro balloon
Crosses second lesion after inflation	Soft LoPro balloon Hydrophilic coating
Ability to dilate at higher pressures	Soft LoPro balloon

OTW Product Drawings

- see figures

Product Design (Common Distal, OTW), Eric Leopold, Dan Cox 8/23/94

Common Distal - Design Options

- Tip Design
  - Long taper (1-1.5mm) and long tip length
  - Medium taper (.75-1.25) and medium tip length
- Tip Sealing
  - Induction sealer
  - Heat nozzle sealer
- Distal Inner Member
  - HDPE with FeO (extended mandrel)
  - HDPE with graphite (extended mandrel)
- Distal Inner Member Dimension
  - .0165"/.0225"
  - .017"/.023"

Common Distal - Design Options

- Distal Outer Member
  - HDPE (extended mandrel)
  - HDPE (flush die)
- Proximal Sealing
  - Induction sealer
  - Heat nozzle sealer
- Radiopaque Marker
  - Gold band
  - Platinum/IR band

New Platform OTW - Design Options

- Proximal Outer Shaft
  - PEEK outer shaft
  - PEK outer shaft
- Proximal Inner Member
  - HDPE with FeO (extended mandrel)
  - HDPE with graphite (extended mandrel)
- Proximal Markers
  - Gold Foil
  - TBD
- Proximal Adaption
  - Single piece injection molded adapter
  - Injection molded adapter with molded adaption cups

New Platform OTW - Design Options

- Mid-Junction Design
  - UV or cyanoacrylate adhesive
  - Long bond, no plasma versus short bond, plasma
- Mid-Junction Process
  - Plasma treatment
  - Corona treatment

New Platform OTW - Current Status

Attribute	New Platform OTW	Design Goal
Track	Sign. better than Edge Similar to Cobra w/o SLP & Hydrophilic	Better than Sleek
Cross	TBD	Competitive with Sleek
GW Movement	Excellent	Equal to Edge
Push	Slightly better than Cobra	Equal to Cobra
Atraumatic Tip	Slightly larger than Sleek	Competitive with Sleek
Recross	Better than Edge (SLP on Edge)	Equal to Sleek
COPS	TBD	Improved over Edge

New Platform OTW - Current Status

Attribute	New Platform OTW	Design Goal
Tip Profile	.030"	≤ .030"
Balloon Profile	.040" (SLP on Edge)	≤ .039"
Distal Shaft Size	2.7 F stepped to 2.9 F	≤ 2.7 F
Prox Shaft Size	3.1 F	≤ 3.1 F
Relation to GC	1 catheter in 6 F GC (poor flow)	1 catheter in 6 F GC
Deflation Time	8 seconds for 3.0 x 20 (PE600) TBD for 4.0 x 40	≤ 8 seconds for 3.0 x 20 ≤ 20 seconds for 4.0 x 40
Shaft Length	135 cm	135 cm

Product Design (Common Distal, OTW), Eric Leopold, Dan Cox 8/23/94

Common Distal - Technical Issues/ Challenges

- Aggressive Tip Sanding
  - Initial studies by Mandy Lee show the potential need for a two step sanding operation (rough followed by fine sanding)
- Tip Seal
  - Further evaluation of tip seal with SLP is needed to verify acceptable yield
- Distal Outer Member
  - Need to verify capability of meeting pressure requirements of 1.5mm SLP balloon
  - Consistency of extrusions needs to be shown
  - Select length of 2.7 F and 2.9 F sections to balance push, track, and deflation times

Common Distal - Technical Issues/ Challenges

- Distal Inner Member
  - Selection of IM ID based on acceptable GW movement
  - Manufacturing acceptability of extended mandrel and graphite
- Merging of Technologies
  - Soft LoPro
  - Hydrophilic Coating
  - E-Beam

New Platform OTW - Technical Issues/ Challenges

- Proximal Outer Member
  - Material availability
  - Acceptability of PEK properties
- Proximal Markers
  - Bondability to PEEK or PEK outer member
- Mid Catheter Junction
  - Adhesive junction to PE
  - Tolerance required for adhesive bonding
- Proximal Adaption
  - Adhesive junction
  - New adapter design to reduce cost

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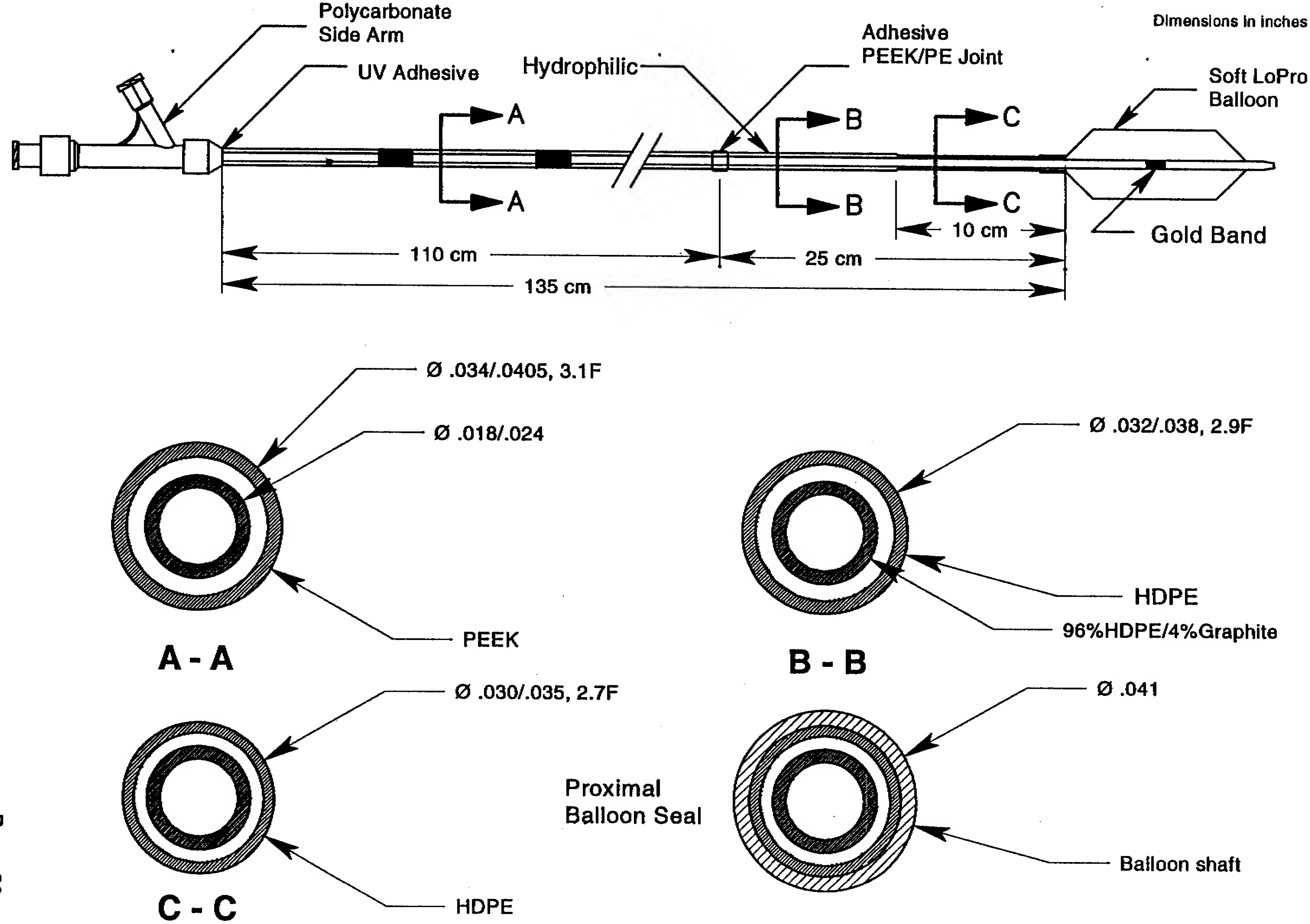
New Platform .014 OTW

Dan Cox
8/23/94
Not to Scale



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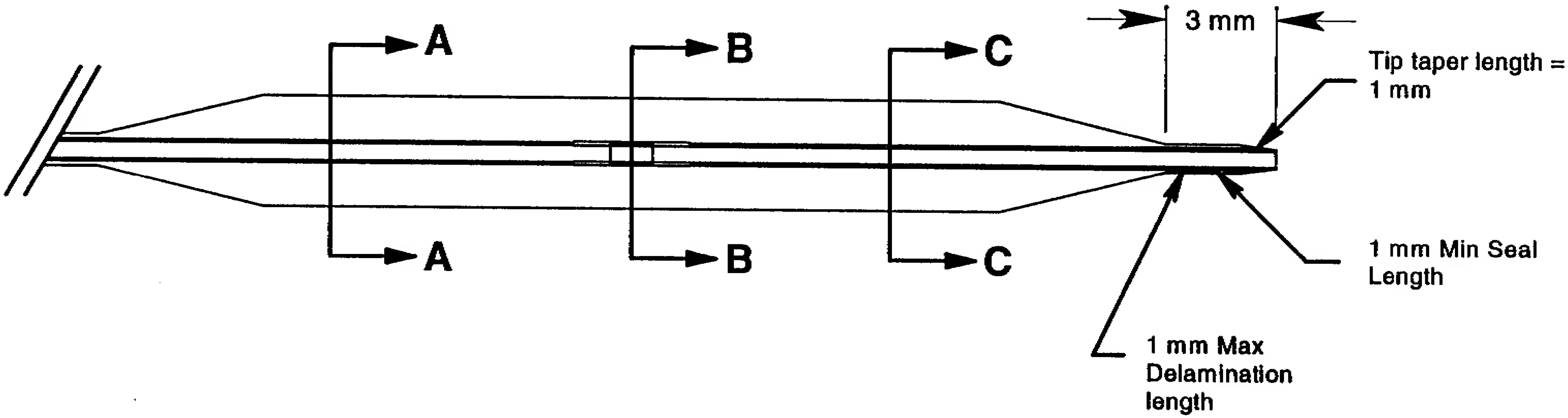
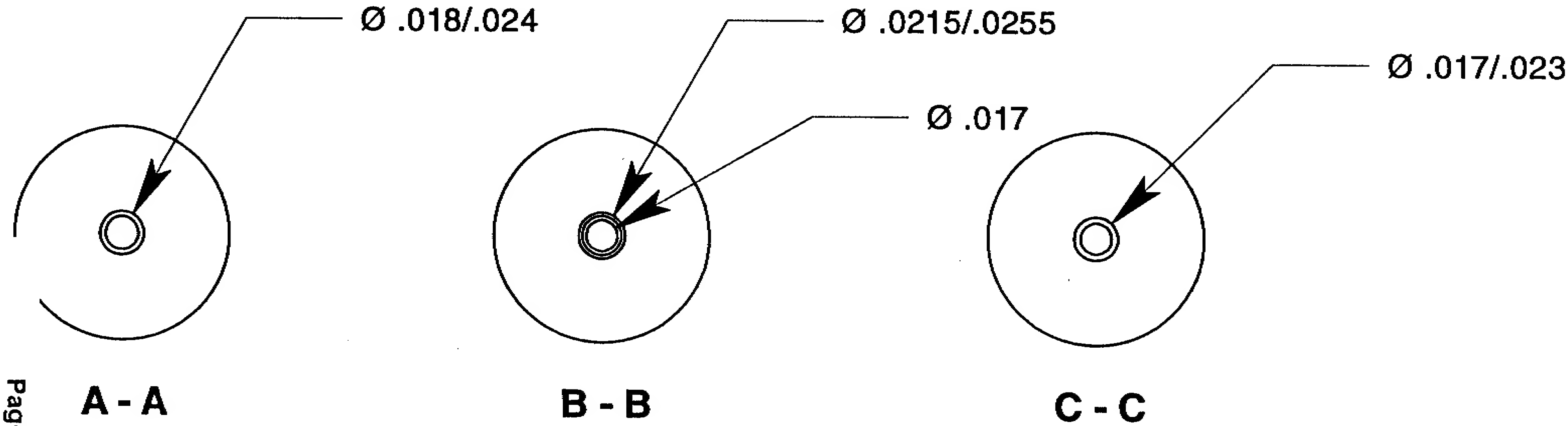
Dan Cox
8/23/94

Balloon and Tip Diagram

3.0 mm Balloon





New Platform RX/OTW Concept Review

New Platform OTW - Heart Model Testing

- *15 in-house heart modeling sessions*
- *4 heart model sessions with physicians*
  - *Dr. Hartzler: SAB Meeting*
  - *Dr. Baim: SAB Meeting*
  - *Dr. Stack: SAB Meeting*
  - *Dr. Stone: at ACS*

(see reports in booklet for details)

New Platform OTW - Heart Model Results

- *Heart modeling (3) OTW shaft designs*
  - *PEEK, Co-axial proximal shaft, elliptical distal*
  - *"PEEK, coaxial proximal shaft, coaxial distal shaft*
  - *Cobra as control catheter*
  - *<.041" sheath as simulated lesion*
- *Results*
  - *Tip Length: shorter, nicer bevel*
  - *Smoothness of shaft:*
  - *Transitions*
    - *Balloon to shaft: Somewhat better, smoother, less abrupt*
    - *Shaft transitions: Somewhat better, less bulky*
  - *Trackability: Significantly better, "smooth and effortless"*
  - *Pushability: Significantly better, "was there before I knew it, no prolapse in the circ or ostium of LAD when pushing against sheath"*

New Platform OTW - Pre-Clinical Testing Plan

- *Continue to evaluate current designs in the heart model using competitive products*
- *Optimize the excised pig heart in-house*
- *Mayo pig study with final design*

Next Platform .014" (OTW) shaft evaluation								
Mayo Clinic animal studies, July 29, 1994								
Dr. Kirk Garratt, Dr. Stuart Higano								
Listed below are the catheters in the order they were evaluated .								
Dr. Garratt's		gw mov	access	cross	comments			
evaluation								
14K		4.0	4.5	3.0	crossed with deep seatinng			
		4.5	4.5	4.5	no guide movement on cross			
co-ax,co-ax (A1)					with modest guide placement			
Dr. Higano's		gw mov	access	cross	comments			
evaluation								
Cobra		2.0	4.0	1.0	could not cross with significant effort			
					with deep seating			
co-ax,co-ax (A5)		3.0	4.0	4.0	crossed w/ modest guide placement			
					and steady push ,no guide bobing.			

Next Platform .014" (OTW) shaft evaluation
Mayo Clinic animal studies, July 29, 1994
Dr. Kirk Garratt, Dr. Stuart Higano

Comments and Conclusions (Co-axial\Co-axial test catheters)

The test catheters evaluated by both investigators performed significantly better in cross than the Sci-Med Cobra or Medtronic 14K.

During Dr. Higano's evaluation the Sci-Med Cobra failed to cross and the test catheter crossed with modest guide placement with no guide "bobing" observed.

Dr. Higano commented that the proximal shaft of the Co-axial/Co-axial test catheter was a significant improvement over the Edge.

The animal study results are consistent with in-house heart modeling.

The animal studies were conducted with PE-600 balloon material on all test devices.

RX Product Features to Address Customer Needs

Customer Need	Product Features
Slides through tortuous artery without resistance	Small distal shaft size Hydrophilic coating Soft LoPro Balloon Tracking Sheath
Crosses difficult distal lesions	Aggressive tip sand Soft LoPro balloon Hydrophilic coating Mid catheter junction
Smooth guide wire movement	Graphite/HDPE extended mandrel fit Coaxial design
Transmits push from back end to distal tip	Reinforced single lumen proximal shaft Mid catheter junction

Dan Cox/Eric Leopold 8/23/94

RX Product Features to Address Customer Needs

Customer Need	Product Features
Atraumatic tip	Aggressive tip seal Small tip diameter Soft LoPro balloon
Crosses second lesion after inflation	Soft LoPro balloon Hydrophilic coating
Ability to dilate at higher pressures	Soft LoPro balloon
Minimize blood loss at RHV	Tracking Sheath
Stores well on table	Reinforced single lumen

Dan Cox/Eric Leopold 8/23/94

RX Product Drawing

- see figures

Dan Cox/Eric Leopold 8/23/94

New Platform RX - Design Options

- Proximal Outer Shaft
  - HDPE (extended mandrel)
  - HDPE (flush die)
  - PEEK
- Proximal Reinforcing Mandrel
  - Stainless Steel
  - New Alloy
- Proximal Markers
  - Gold Foil (HDPE outer shaft)
  - ?? (PEEK outer shaft)
- Proximal Adaption
  - Injection molded adapter with molded adaption cup
  - Insert molded adapter

Dan Cox/Eric Leopold 8/23/94

New Platform RX - Design Options

- Mid-Junction Design
  - Transition with polyimide and coil (HDPE outer shaft)
  - Transition with polyimide (PEEK outer shaft)
- Mid-Junction Process
  - Seal with hot box (HDPE outer shaft)
  - Seal with hot box, plasma treat, and adhesive (PEEK outer shaft)
- Tracking Sheath

Dan Cox/Eric Leopold 8/23/94

New Platform RX - Current Status

Attribute	New Platform RX	Design Goal
Track	Better than Elipse	Better than Europass
Cross	Better than Elipse	Competitive with Europass
GW Movement	Better than Elipse	Better than Elipse
Push	Slightly less than Elipse	Equal to Elipse
Atraumatic Tip	Slightly larger than Europass	Competitive with Europass
Recross	Better than Elipse	Equal to Europass
COPS	TBD	Improved over Elipse

Dan Cox/Eric Leopold 8/23/94

New Platform RX - Current Status

Attribute	New Platform RX	Design Goal
Tip Profile	.030"	≤ .030"
Balloon Profile	.040" (SLP on Edge)	≤ .039"
Distal Shaft Size	2.7 F stepped to 2.9 F	≤ 2.7 F
Prox Shaft Size	2.8 F	≤ 2.8 F
Relation to GC	1 catheter in 6 F GC (poor flow) 1 catheter / 2 GW in a 7 F GC	1 catheter in 6 F GC 1 catheter / 2 GW in a 7 F GC
Deflation Time	5.5 seconds for 3.0 x 20 TBD for 4.0 x 40	≤ 8 seconds for 3.0 x 20 ≤ 20 seconds for 4.0 x 40
Shaft Length	135 cm	135 cm
Exchange Length	25 cm	25 cm

Dan Cox/Eric Leopold 8/23/94

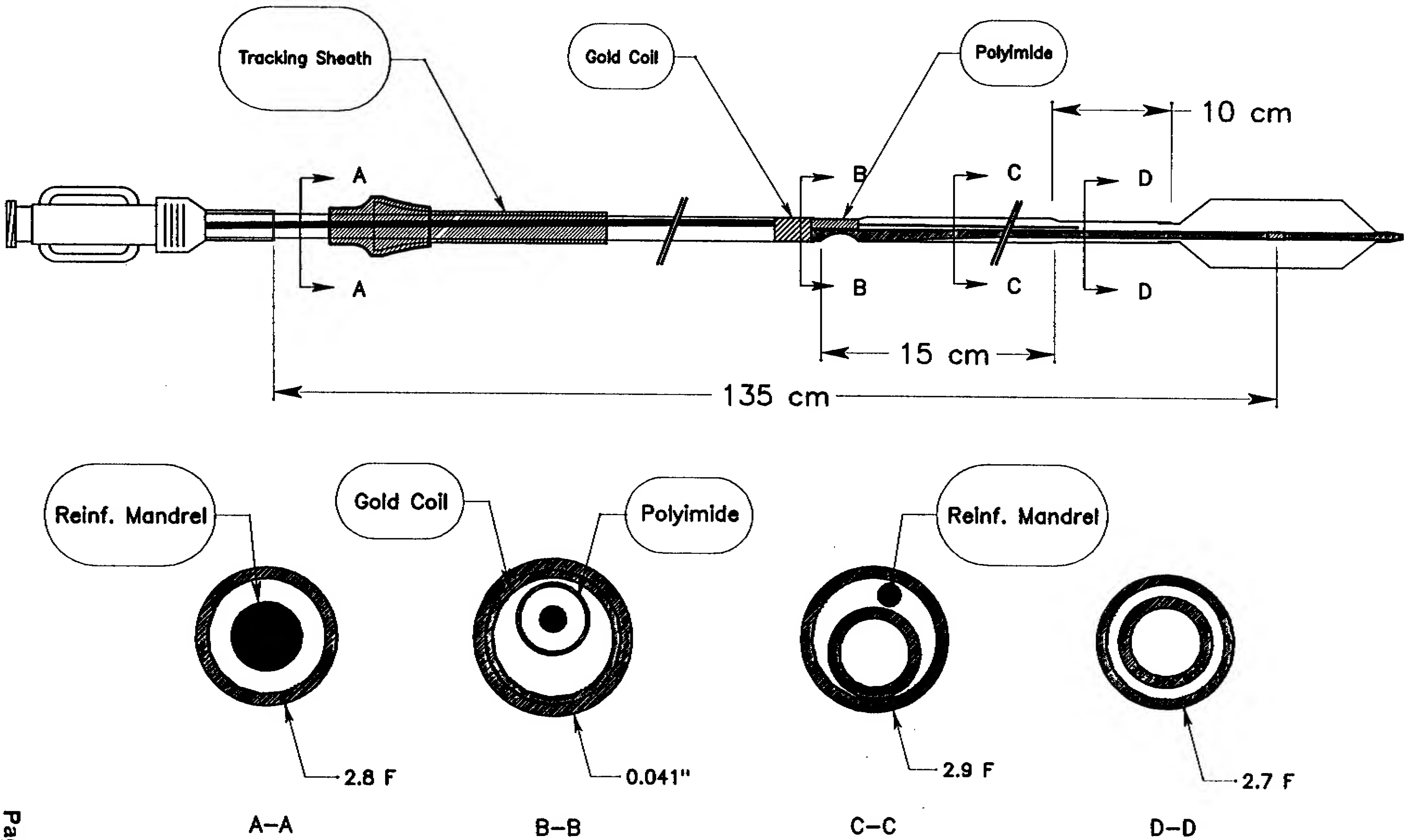
New Platform RX - Technical Issues/ Challenges

- Proximal Shaft
  - Balancing the needs of push, flexibility, deflation times, and shaft size
- Proximal Markers
  - Bondability to PEEK outer shaft
- Mid Catheter Junction
  - Tolerances required for adhesive bonding
  - Need for plasma treating a subassembly before adhesive bonding

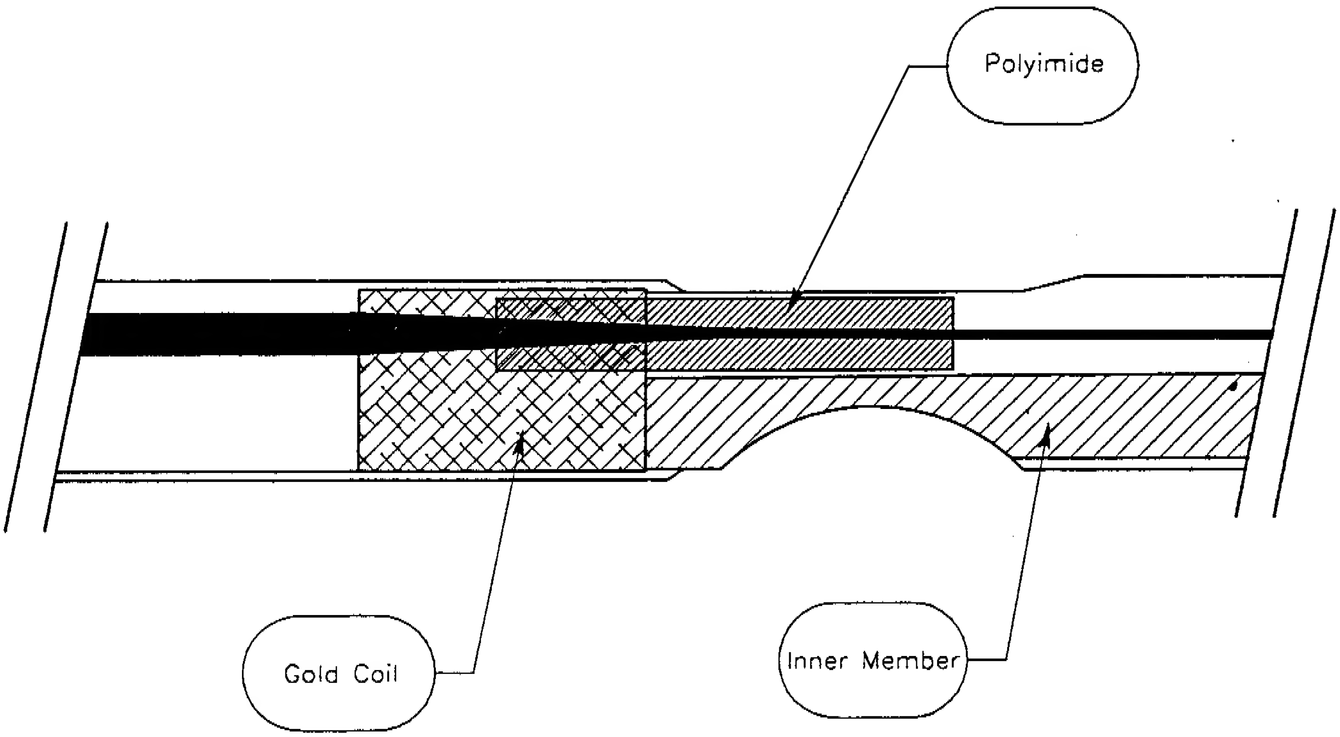
Dan Cox/Eric Leopold 8/23/94

Product Design (RX), Eric Leopold, Dan Cox 8/23/94

New Platform RX



Eric Leopold 8/23/94



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Mid Catheter Junction – New Platform RX

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Not to Scale	Eric Leopold	8/18/94	

New Platform RX - Heart Model Testing

- Peel-away versus non peel-away
- PE600 versus Nucrel versus X1400 versus Nylon versus Soft LoPro Balloon Materials
- Elliptical versus coaxial
- Various shaft materials
- Hypotubes versus reinforced single lumen proximal shafts
- Mid-catheter transition evaluations

New Platform RX - Heart Model Results

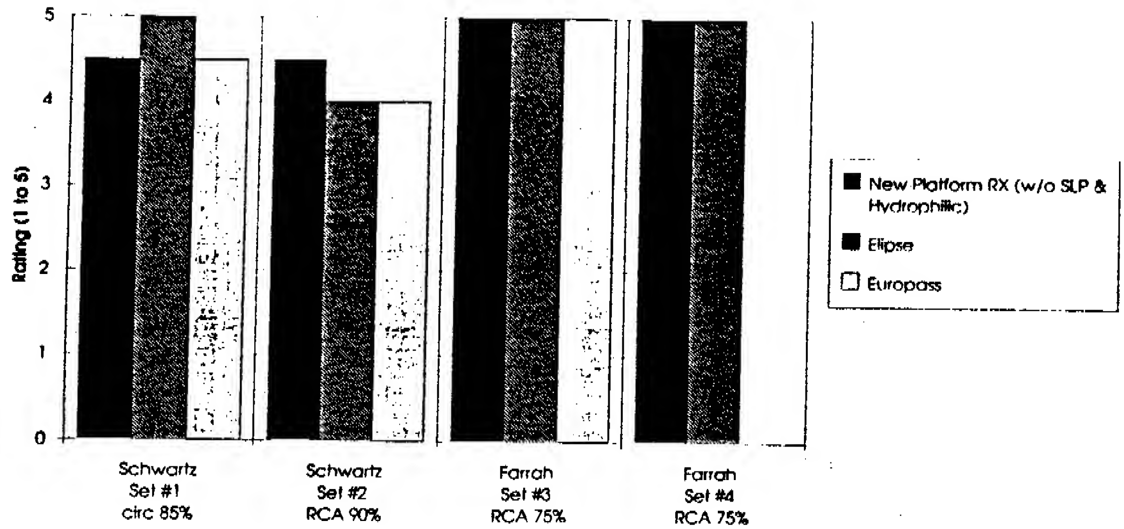
- Improved distal tip taper
- Improved proximal seal
- Better guide wire movement
- Improved mid-catheter transition
- Improved track
- Easier handling of proximal shaft
  - Perception of less push
- Improved cross-recross over PE600

New Platform RX - Pre-Clinical Testing Challenges

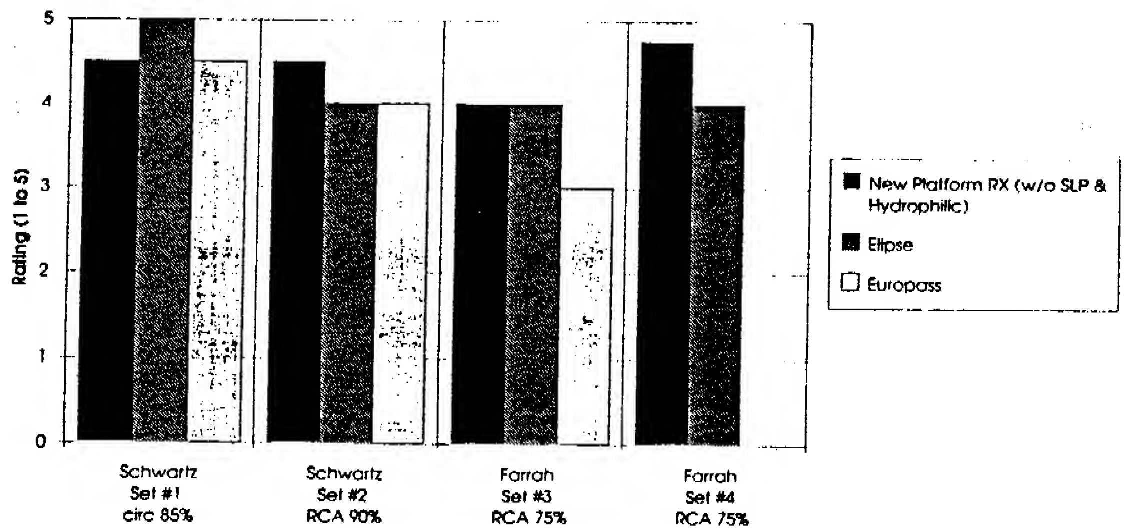
- Evaluation of cross/recross versus competitive balloon catheters
  - Heart Modeling
  - Synthetic lesion
  - Perfused pig heart with Mayo hearts
  - Lesion animal model

New Platform RX
Animal Study March 9-10, 1994

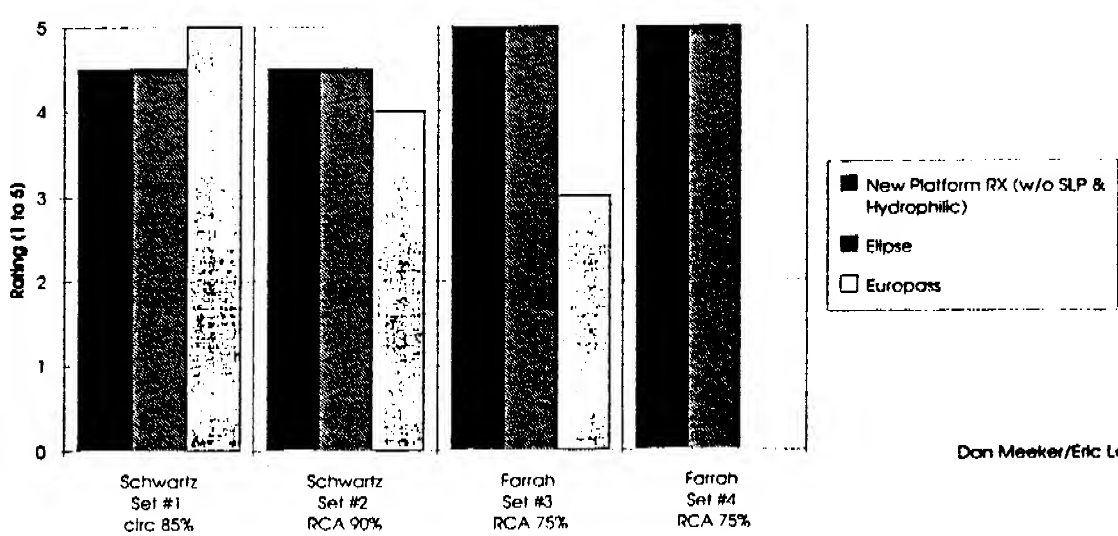
Cross



Access



Guidewire Movement



Dan Meeker/Eric Leopold 8/23/94

Next Platform .014" (RX)								
Mayo Clinic animal studies, March 9-10, 1994								
Dr. Rob Schwartz , Dr. Tony Farrah								
Schwartz /set #1 pig 455/circ 85%								
		gw mov	access	cross	comments			
Elipse #1		4.5	5.0	5.0				
Europass #1		5.0	4.5	4.5				
SRCO #1		4.5	4.5	4.5	Dr. likes suppport of the shaft best			
Schwartz /set #2 expired pig #455 /90%RCA								
Elipse #1		4.5	4.0	4.0				
Europass #1		4.0	4.0	4.0				
SRCO #1		4.5	4.5	4.5	smoother track than Elipse			
					or Europass			
Farrah/set #3/pig #456/RCA 75%								
Elipse #2		5.0	4.0	5.0	lesion not optimal for cross			
Europass #2		3.0	3.0	5.0	balloon feels bulkier			
SRCO #2		5.0	4.0	5.0				
Farrah/set #4/expired pig #456/RCA 75%								
Elipse #3		5.0	4.0	5.0				
SRCO #4		5.0	4.75	5.0	significantly better track			

PRELIMINARY PRODUCT FMECA

PRODUCT: Distal Shaft of .014 New Platform Catheter (OTW & RX)
PROJECT ENGINEERS: Dan Cox, Eric Leopold, & Larry Wasicek

DATE: 8/18/94
REV.: A
PREPARED BY: Dan Cox, Eric Leopold, Victor Nguyen, Diem Ta, & Larry Wasicek

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
4	Distal shaft outer member	Provides an inflation/deflation lumen.	1. Kinks.	1. Long deflation time 2. Poor trackability and pushability	Handling	Visually inspect shaft for kinks throughout manufacturing.	4	5	7	140
			2. Large OD	1. Poor trackability 2. Poor visualization	Improper necking	Measure OD with snap gauge.	2	2	1	4
			3. Small ID	Long deflation time	Extrusion	1. ID is measured in receiving inspection. 2. Size of mandrel used for necking process	2	4	1	8
			4. Ruptures.	1. Pressure loss 2. Dissection	1. Mechanical damage 2. Flaw in extrusion	1. Visual inspection of tubing for anamolies in receiving inspection. 2. Leak test complete catheter to 150 psi, sheathed.	4	9	10	360

PRELIMINARY PRODUCT FMECA

PRODUCT: Proximal Shaft of RX .014 New Platform Catheter
PROJECT ENGINEERS: Eric Leopold

DATE: 8/22/94
REV.: A
PREPARED BY: Eric Leopold & Diem Ta

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
3	Proximal shaft outer member	Provides an inflation/deflation lumen.	1. Kinks.	1. Long deflation time 2. Poor trackability and pushability	Handling	Visually inspect shaft for kinks throughout manufacturing.	4	5	7	140
			2. Large OD	1. Poor trackability 2. Poor visualization	Extrusion	Receiving Inspection measures OD with snap gauge.	2	2	1	4
			3. Small ID	Long deflation time	Extrusion	Receiving inspection measures ID.	2	4	1	8
			4. Ruptures.	1. Pressure loss 2. Dissection	1. Mechanical damage 2. Flaw in extrusion	1. Receiving inspection visually inspects tubing for anamolies. 2. Leak test complete catheter to 150 psi, sheathed.	2	7	10	140

RXPSHFME.XLS

New Platform RX/OTW - Manufacturing Issues/ Risks

- Hydrophilic Coating (OTW and RX)
  - Process Flow
- Junction with Coil (RX only)
  - Process Flow
  - Yield
- Coil (RX only)
  - Make versus Buy
  - Material
- Reinforcing Mandrel/Grinding (RX only)
  - Make versus Buy
  - Annealing/discoloration
  - Loading and positioning mandrel

New Platform RX/OTW - Manufacturing Issues/ Risks

- Adhesive Bonding (RX only assuming PEEK)
  - Process flow/cure time
  - Seal integrity
  - Pull strength
  - Yield
- Adhesive Bonding (OTW only)
  - Balloon/mid-shaft and proximal adaption
- Insert Molding (OTW and RX)
  - Process flow
  - Yield

New Platform RX/OTW - Manufacturing Issues/ Risks

- Graphite Inner Member (OTW and RX)
  - Compounding/holes in lumen
  - Extrusion yield
- Extended Mandrel Extrusions (OTW and RX)
  - Extrusion yield

New Platform RX/OTW - Manufacturing COPS Estimation

- Cost analysis performed on initial concept designs
  - Using finance COPS evaluation tool (K. Phillips)
  - Estimates based on preliminary manufacturing processes
  - Included assumptions on yields, rates, and overhead
- Eliminated elastinite concept based on high COPS design
- Maximum COPS savings achieved through coaxial design

New Platform RX/OTW - Manufacturing COPS Estimation

- COPS estimation of coaxial distal end design decision
  - Initial estimates OTW COPS = Edge range (+/- 10%)
  - Initial estimates RX COPS = Streak range (+/- 10%)
  - Hydrophilic coating = $10 to $15 COPS increment

New Platform RX/OTW - Manufacturing Site

R&D

Concept Review

R & D / SDC

Design Review

SDC to Manufacturing (Temecula)

Integration Review

Manufacturing (Temecula)

Final Project Review

Manufacturing (Temecula)
International Units Completed in EDC

Post Market Review

New Platform RX/OTW - Common Distal Shaft Benefits

- Same Materials
  - Inner Member
  - Distal Outer Shaft
  - Balloon Tubing
  - Gold Band
  - Final Balloon Sheath
- Same Balloon Molds
  - Less engineer support to design/suppot
  - Less molds required
  - Less documentation
- General Benefits
  - Same documentation will have to be managed
  - Engineering support may require less

New Platform RX/OTW - Common Distal Shaft Benefits

- Identical Process
  - Processes
    - Balloon blowing
    - Proximal balloon shaft necking
    - Tip seal
    - Gold band recovery
    - Distal shaft necking
  - Benefits
    - Same equipment
    - Same tools and fixtures
    - Operators interchangable
- Future Design and Process Improvements
  - New technologies will interchange from OTW and RX

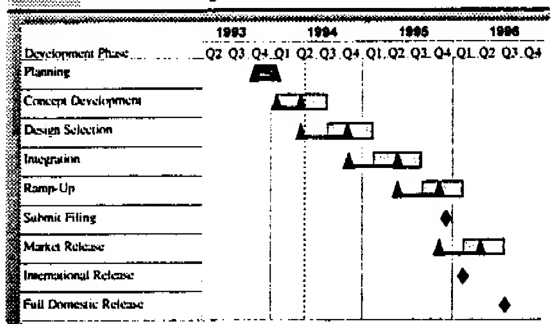
New Platform RX/OTW - Key Factors of DFM

- Safety
- Quality
- GMP Compliance
- Innovation
- Cost
- Environment

Project Schedule

- Current Project Schedule
- Aggressive Approach to Design Selection Phase Activities

Current Project Schedule



Aggressive Approach to Design Selection Phase

- Objective: Significant improvment on current schedule for Design Review (2/95)
- Benefit: Creates the potential for an earlier market release and provides momentum going into 1995
- Assumptions Required:
  - Team will be able to make rapid decisions
  - Necessary resources will be available
  - Technologies will meet current schedules
  - Product design limitations are acceptable
  - Increased risks are acceptable

Resource Issues

- Additional R&D Staff
  - RX Engineer
  - RX Tech
  - OTW Tech
- SDC/Production Support
  - Balloon Supply
  - Catheter Builds
- Sufficient commitment/priority from current resources

Summary

- New Platform catheters will meet current project goals, with the possible exception of "equal cross"
- Significant, but not unreasonable, technical risks need to be addressed in the following areas:
  - balloon
  - coating/sterilization
  - PEEK/PEK
  - catheter design
- Potential exists to accelerate schedule from the current mid-96 domestic release.

Recommendations

- Accept "competitive" as crossing goal
  - Current designs will significantly improve competitiveness of ACS product line
  - No reasonable alternatives improve on this performance dimension
  - Further evaluation and testing would detract from completing design work
- Proceed with Design Selection
- Evaluate whether an aggressive schedule is appropriate, report to Sr. Staff on 9/15/94
  - Potential for success in meeting aggressive schedule
  - Degree of increased risk due to aggressive schedule
  - Performance which might be "left on the table"

The expected customer use of these products is the same as that of currently marketed OTW and RX dilatation catheters. For this reason, only the following changes are anticipated to the "Unified IFU" currently planned for ACS Products:

Potential Changes
Unified Instruction for Use

- Product Description
  Remove description of the use of Dual Lumen tubing
- Coil Clip
  Remove instructions indicating use of Coil Clip
- Peel-Away
  Remove instructions indicating use of peel-away
- Tracking Sheath
  Insert instructions indicating proper use of tracking sheath
- Indication for use
  Remove indication for drug infusion through guide wire lumen of OTW

rsejna 8-23-94

It is the expected that the New .014 Platform catheters will require a PMA-s filing with the FDA. Requirements for this filing are described on the following pages.

PREMARKET APPROVAL SUPPLEMENT APPLICATION (PMA/S)

- Submit before making change affecting the safety and effectiveness of the device for which a PMA is approved.
- Burden for determining whether a supplement is required is the responsibility of the PMA holder.
- PMA/S required for changes if affect safety or effectiveness. These include but not limited to:

  (1) New indications for use
  (2) Labeling changes
  (3) Different facility or establishment to manufacture, process or package the device
  (4) Changes in manufacturing facilities, methods, or quality control procedures
  (5) Changes in sterilization procedures
  (6) Changes in packaging
  (7) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device
  (8) Extension of the expiration date based on new data obtained by a protocol not approved by FDA

- Same information that is required for PMA and is limited to information to support the change.

J.P. Palin 8/22/94

CONTENTS OF A PREMARKET APPROVAL APPLICATION (PMA)

(1) Name and address of the applicant
(2) Table of Contents
(3) Summary of the contents of the application
(4) Description of the device
(5) Reference to performance standards
(6) Technical Information
(7) Justification for one Investigator
(8) Bibliography
(9) Samples of the device, if requested
(10) Labeling
(11) Environmental assessment
(12) Other information

J.P. Palin 8/22/94

New .014 Platform Design Decisions - Concept Development

The following decisions were made during the Concept Development phase of the New .014 Platform OTW/RX product development effort (Project #1315). A short justification is provided for each decision, with additional detail provided through references. All referenced documents will be available in the Design History File for this project, contact ACS Document Control for further information.

1. Elimination of Peelaway on RX product
2. Common distal shaft for RX and OTW catheters
3. Soft LoPro balloon material
4. PEEK or PEK proximal shaft material for OTW catheter
5. Reinforced single lumen design for the RX catheter proximal shaft
6. PE based inner member for RX and OTW catheters
7. Aggressive tip sanding method
8. Coaxial distal shaft design

New .014 Platform Design Decision Justification

Design Decision: **Elimination of Peelaway on RX Product**
Justification Author(s): Eric Leopold [signature] 8/23/94
Eric Peterson [signature] [date]
sign date

Date: August 2, 1994

Describe Decision and Options Considered

Decision to drop the "peelaway" feature from the New .014 Platform RX product. The two options considered were a 30cm distal section riding on the wire with a peelaway feature and a 25cm distal section without peelaway.

Describe Rationale for Decision and Summarize Supporting Data

While peelaway has always been a selling point for ACS RX products, cardiologists have indicated that this feature is highly desireable as a "convenience" item, but that they would sacrafice it to obtain improved performance. This had also been reflected in the wide acceptance and market share of the Scimed Express catheter, prior to its removal from the market.

Several international accounts had indicated an actual preference for non-peelaway RX catheters, in part due to their comfort level with Schneider products.

Several concrete factors argued in favor of elimination of the peelaway feature, including the following:

Peelaway adds $10+ to the COPS of the catheter
Peelaway reduces commonality with OTW catheter
Peelaway adds 6-9 months to the development cycletime
Peelaway requires slightly larger distal shaft sizes
Peelaway eliminates coaxial designs from consideration
Peelaway potentially reduces trackability of the catheter

List References (reports, memos, lab books, etc.)

Peelaway Summit #1 Meeting Minutes, Jon Becker, 11/5/93
Peelaway Summit #2 Meeting Minutes, Jon Becker, 12/10/94
Concept Template Draft, Eric Peterson, 1/24/94

Design Decision: **Common Distal Shaft for RX and OTW Catheters**
Justification Author(s): Eric Peterson ____________ sign ________ date
Date: August 8, 1994

Describe Decision and Options Considered

The New .014 Platform project was initiated with the explicit goal of delivering a set of products which had a common distal 25 cm section. While the viability of this concept has been examined, no other options have been considered.

Describe Rationale for Decision and Summarize Supporting Data

The "working end" of the balloon catheter is the distal 25 cm. This section also requires the greatest amount of development and testing since it determines most of the performance of the catheter, has strong interactions with the balloon, etc.. The common distal end seeks to leverage the development work done on one platform and directly apply it to the other.

Early in development, numerous potential downsides, such as reduced performance, were evaluated. To date, none of these appear to be significant. There will be a slight direct labor impact on the RX product design; however, this should be more than offset by indirect savings in other areas of manufacturing.

List References (reports, memos, lab books, etc.)

Concept Template, draft 1/24/94, Eric Peterson

New .014 Platform Design Decision Justification

Design Decision: **Soft LoPro balloon material**
Justification Author(s): Eric Peterson sign date
Date: August 22, 1994

Describe Decision and Options Considered

The New Platform catheters will utilize the Soft LoPro balloon material. Other balloon materials considered include the current PE-600 material and the "Next Gen Balloon".

Describe Rationale for Decision and Summarize Supporting Data

PE-600 does not meet the basic project requirement of having an extended range of inflation pressures. The Next Gen Balloon does not meet the timing requirements of this project. Soft LoPro provides improved burst pressures, greater softness/recross, and slightly smaller profiles with technology similiar to current PE-600.

List References (reports, memos, lab books, etc.)

Concept Template Draft, Eric Peterson, 1/24/94

Design Decision: **PEEK or PEK Proximal Shaft Material for OTW Catheter**
Justification Author(s): Dan Cox
Eric Peterson

Date: August 22, 1994

Describe Decision and Options Considered

Selection of PEEK, or comparable, high performance thermoplastic for the stiff component of the proximal shaft. Primary alternate shaft design considered was the "ACX V" Elastinite catheter design with a metal NiTi inner member providing stiffness.

In addition, numerous other thermoplastics and several composite structures (e.g. polyimide with stainless steel mandrels) were considered. Non-coaxial, dual lumen designs were also evaluated during the design process.

Describe Rationale for Decision and Summarize Supporting Data

At the initiation of this project, the preferred OTW design utilized the Elastinite inner member. However, as COPS evaluations were conducted, it became clear that Elastinite designs would not meet the aggressive manufacturing cost targets set for the project. Based on feedback from senior management that cost targets could not be relaxed, a two pronged approach was taken:

1. Identify means to reduce the overall cost of the Elastinite catheter
2. Identify a low cost, high performance alternative to Elastinite

The current design is based upon the second prong of this approach, a high performance thermoplastic material which provides very high stiffness and good kink resistance. Evaluation in heart models by ACS Clincal Research and Dr. Greg Stone demonstrated that this material, used as an outer member, provides similiar performance to the higher modulus Elastinite used an inner member. (These were the two primary design options.)

Based on comparable performance and significantly lower cost (approx. $30 advantage), the PEEK material was selected. Following this selection, a technical review of PEEK and related processes was held to confirm the acceptability of this material for use on this product.

List References (reports, memos, lab books, etc.)

New .014 Platform team decision not to pursue Elastinite OTW catheter, E. Peterson, 5/6/94
ACX V Heart Model and Animal Study Results, 1993
Summary of Materials under Evaluation for Next OTW, Larry Wasichek, 3/16/94
Expected performance of current OTW design options, Dan Cox, 5/2/94
Materials from Senior Staff Presentation, 2/11/94
Feedback on Senior Staff Presentation, Ginger Howard, 2/28/94
High performance low cost Elastinite designs for RX & OTW, Steve Johnson, 2/15/94
Next .014 Catheters with Elastinite, Mike Clayman, Steve Johnson, 3/11/94
Peek Technical Review materials, Bob Ainsworth, 5/25/94

Design Decision: **Reinforced single lumen design for the RX catheter proximal shaft**
Justification Author(s): Eric Leopold 8/23/94
Eric Peterson
sign date
Date: August 22, 1994

Describe Decision and Options Considered

The proximal shaft of the RX product will use a reinforced single lumen (RSL) design. This design employs a ground stainless steel mandrel to provide stiffness inside a single lumen polymer tubing which acts as an inflation/deflation lumen for the balloon.

Other designs considered include the RX Elipse stainless steel hypotube and an Elastinite (NiTi) hypotube. Either of these hypotubes could be designed with or without the PE jacket currently used on the Elipse product.

Describe Rationale for Decision and Summarize Supporting Data

The stainless steel hypotube was eliminated from consideration by the initial definition of the project, due to its inherent "springiness". In addition, the other design options provide for fewer customer returns due to kinked and broken hypotubes.

The Elastinite hypotube design had several significant advantages over the RSL design. These include a singnificantly smaller OD (2.4 vs. 2.8 French), better deflation times, and slightly better push transmition. This design was also non-springy and non-kinkable.

The RSL design meets project goals for shaft size (2.8 French) and deflation times and also provides good push with a non-springy, non-kinkable shaft. However, the major advantage of the RSL design is manufacturing cost, with an approximately $30 advantage over Elastinite. Additional discussion of Elastinite costs and references please see the writeup on Design Decision: Proximal Shaft Material for OTW Catheter.

The proximal shaft design decision is consistent with the decision made for the RX Passport II/Visa project during their concept review.

List References (reports, memos, lab books, etc.)

Design Decision: Proximal Shaft Material for OTW Catheter
Passport II Concept Review, John Shanahan, 3/24/94
Testing of Proximals Shaft Designs, Eric Leopold, 1/24/94
Heart Model of New Platform RX .014, 2/24/94
Performance of coaxial vs. elliptical RX catheters, Eric Leopold, 4/28/94

Design Decision: **PE based Inner Member**
Justification Author(s): Eric Peterson [signature] 8/24/94
Eric Leopold [signature] 8/23/94
sign date
Date: August 22, 1994

Describe Decision and Options Considered

The New .014 Platform catheters will use a PE based inner member, either as a blend of high and low density materials or as 100% HDPE. The inner member may or may not be compounded with graphite. Other material families considered were nylons and PEBAX. The use of a Hytrel material was discussed but not tested for this project.

Describe Rationale for Decision and Summarize Supporting Data

The PE based inner members were comparable or better in performance characteristics (guidewire movement, inner member collapse) than any of the alternative materials. They also pose the lowest technical risk in combination with the PE-based Soft LoPro balloon material since current heat sealing technology can be used.

List References (reports, memos, lab books, etc.)

Protocol Report #92-020, Eric Leopold, 5/20/94
Protocol Report #92-021, Eric Leopold, 5/23/94

New .014 Platform Design Decision Justification

Design Decision:	**Aggressive tip sanding method**		9/27/94
Justification Author(s):	Eric Peterson		8/24/94
	Dan Cox		8/23/94
	Eric Leopold	sign	date
Date:	August 22, 1994		

Describe Decision and Options Considered

New Platform catheters will leverage induction seal and aggressive tip sanding technologies from the Low Cost Edge and Avant Edge projects. Options for creating the balloon seal included adhesives and conventional heat seal in addition to the selected induction heat seal. Options for forming or shaping the tip were aggressive sanding, shaving, and an adhesive fillet.

Describe Rationale for Decision and Summarize Supporting Data

The selected direction provides comparable or better results with less technical risk and greater leverage of other development efforts.

Adhesive seals and fillets would require significant development to reach necessary process capabilities. In addition, the maximum seal OD for adhesives would probably be larger than the heat seal options. The induction heat seal equipment and process has been developed in manufacturing to improve process yields vs. the current heated air equipment.

All of the shaping options (adhesive fillet, shaving, and aggressive sanding) produced similiar results based on customer feedback. The aggressive sanding option was selected because it has the least technical risk, lowest effort required to develop, leverages other development projects, and best fits efforts to achieve an aggressive schedule for the New Platform product release.

List References (reports, memos, lab books, etc.)

Distal Tip Summit, 1/20/94, Joann Heberer, Pat Urasaki, Dave Jacobson
Tip Seal Options, 2/94, Joann Heberer
Tip Seal Recommendation, 6/14/94, Mike Buchin, Mandy Lee
Adhesive Tip Seals with Soft LoPro, 4/19/94, Pat Urasaki
Tip status/update, 5/19/94, Mike Buchin
Summary of tip evaluations from SAB meeting, 3/17/94, Margo Zaugg
Opportunities for enhancing tip performance, 6/2/94, Mike Buchin, et. al.

Design Decision:	**Coaxial distal shaft design**		
Justification Author(s):	Eric Peterson		
	Dan Cox		8/24/94
	Eric Leopold		8/23/94
		sign	date
Date:	August 15, 1994		

Describe Decision and Options Considered

The distal shaft of the New Platform catheters will be a coaxial design. Both coaxial designs and non-coaxial, elliptically shaped dual lumen shafts were evaluated.

Describe Rationale for Decision and Summarize Supporting Data

The primary driver for the final shaft design decision was a concern that doctors would perceive a potential safety issue with "balloon bowing" which occurred on non-coaxial designs using the Soft LoPro balloon material. Available data does not allow a conclusion to be drawn as to whether the perceived issue is or is not of real clinical significance. However, since the majority of physicians with whom we discussed the behavior indicated some level of concern, the decision was made to proceed with the lowest risk option, a coaxial design.

Prior to determining that the bowing occurred on non-coaxial designs, the two options were very close. Performance in heart models and animal studies was very close, with perhaps a slight edge for coaxial. The marketing message for elliptical provided a strong incentive to go with the elliptical dual lumen design. Manfuacturing had pros and cons for both options.

List References (reports, memos, lab books, etc.)

Soft LoPro/Coax Decision, draft, Gary Schneiderman, 8/11/94
Performance summary, coaxial vs. elliptical, Eric Peterson, 8/1/94
Catheter bowing study, Eric Leopold, 7/25/94
Bowing Force Study, Eric Leopold, 8/2/94
Relationship between mm of linear growth and bowing, Eric Peterson, 8/3/94
Coaxial vs. Elliptical summary, Chris Haig, 7/25/94
Soft LoPro Balloon Growth & Bowing Clinical Eval Meeting 1, Jon Becker, 8/1/94
Soft LoPro Balloon Growth & Bowing Clinical Eval Meeting 2, Jon Becker, 8/4/94
Preliminary Recommendation, meeting minutes, Eric Peterson, 3/31/94
Distal Shaft Decision feedback, Mika Nishimura, 4/20/94
Coaxial vs. Elliptical shaft size comparison, Eric Leopold, 6/3/94

Heart Modeling (ACX 5 + .014 Platform: OTW)

2/19/93	ACX 5	Polyimide with .010 wire transition to HDPE, PE600 balloon, graphite inner member
5/18/93	ACX 5 Shafts:	1. ACX 5: polyimide s/s (2 wires) 2. ACX 5: Elastinite IM 3. PEEK 4. ACX 5: polyimide s/s (1 wire)
12/9/93	ACX 5	1. Surlyn tip 2. Attane tip
12/21/93	ACX 5	ACX 5 with tapered Elastinite
1/25/94	ACX 5	Variations: 1. Peek outer shaft to balloon graphite/PE inner inner member 2. Peek outer shaft to alathon intermediate shaft. Spiral cut on Peek at transition, graphite PE inner member 3. Peek outer shaft to alathon intermediate shaft 40cm of Peek inner member to graphite, PE distal 4. Peek outer shaft to alathon intermediate shaft 120cm Peek inner member to graphite PE 5. Elastinite proximal, polyimide transition Prism balloon, clear Quantum intermediate inner member 6. *Elastinite proximal, polyimide transition graflex intermediate inner member *Excellent in track and push, less the Edge in guide wire movement

4/27/94 Dr. Stone, heart model session: .014 Platform OTW:

1. Peek
2. *Elastinite
3. Peek (second sample of #1)
4. *Elastinite (second sample of #2)

*Rated the highest in track, push, guide wire movement

6/24/94 .014 Platform .014 OTW:

1. *Peek proximal shaft .0325/.039, graphite inner member, coaxial
2. Elliptical distal shaft of 83 HDPE/13 LL DPE/4 graphite, similar proximal

*Trackability: smooth into the septal and diagonal
*Pushability: seemed smoother, more flowing effect pushing into the diagonal
*Guide wire movement somewhat better than control Edge

3/24/94 Peek .014 Platform OTW:

1. Coaxial Peek stiff shaft, graphite/PE inner member, 3.0 PE 600 balloon
2. Coaxial Peek 5cm of Peek in inflation lumen at junction from coaxial to elliptical
3. Coaxial Peek - 10cm Peek elliptical
4. Coaxial Peek 10cm polyimide elliptical

3/29/94 .014 Platform OTW:

1. Coaxial proximal end with Peek stiff shaft and graphite/PE inner member. Elliptical distal end with 5cm of Peek at transition graphite/PE inner member under balloon
2. Coaxial with Peek stiff shaft and graphite/PE inner member, alathon distal shaft with 3.0 PE 600 balloon
3. Coaxial Elastinite w/graphite/PE inner member, alathon outer shaft, PE 600 3.0mm balloon
4. Elastinite inner member, alathon outer shaft proximal, elliptical distal end, stainless steel core at junction to Elastinite

5/20/94 .014 Platform OTW:

1. Coaxial OTW, Peek proximal outer shaft, graphite PE inner member alathon 6210 distal, shaft 2.7 Fr, PE 600, 3.0mm balloon
2. Coaxial proximal Peek outer shaft, graphite PE inner member 75% HDPE/25% LLDPE elliptical distal shaft between elliptical distal and Peek, 3.0mm PE 600
3. Same as #2 except has 20cm intermediate alathon stiff shaft between elliptical distal and Peek, 3.0mm PE 600

5/27/94 .014 Platform OTW:

1. Coaxial distal Peek proximal, graphite/PE inner member alathon 6210 distal outer shaft 2.9Fr. to 2.7 Fr., 3.0mm PE 600 balloon
2. Elliptical distal, coaxial proximal 3.0 Fr. Peek, graphite/PE inner member distal necked from .029/.049 to .024/.045 3.0 PE 600 balloon

6/20/94 .014 Platform OTW:

1. Peek proximal outer shaft, graphite/PE inner member, coaxial proximal elliptical dual lumen distally, dual lumen is HDPE (clear)
2. *Same as #1 except dual lumen is 83% HDPE/13% LLDPE/4% graphite
3. Same as #1 except dual lumen is 75% HDPE/25% LLDPE (white)

*The best overall

7/1/94 .014 Platform OTW:

1. *Peek proximal shaft with graphite/PE inner member coaxially: distal end is 83 HDPE/13 LLDPE/4 graphite, elliptical dual lumen 3.0 PE 600 balloon distal and has .015/.0175 polyimide in distal 25cm of inflation lumen, also moved Peek/elliptical junction from 30 to 25cm from balloon
2. Same as #1 except only has .013/.017 polyimide for 4cm at Peek junction, also has .006" stainless steel mandrel in inflation lumen from proximal adaption to proximal balloon seal
3. Has continuous dual lumen (same distal end of #1 and #2), from proximal adaption to balloon. Has stepped mandrel .012 to .006 in inflation lumen. Step is 25cm from balloon .006" goes to proximal balloon seal distal lumen is necked for 13cm.
4. Same as #3 except distal lumen is only necked at proximal balloon seal, not for 13cm

*Best in track and guide wire movement

7/8/94 .014 Platform OTW:

1. Eliptical distal shaft, same as Elipse
2. *Coaxial shaft

*Best overall performance

March 21, 1994
TO: Dan Cox
Jon Becker
FROM: Margo Zaugg · Margo
RE: Summary of ACX V evaluation from 3/13/94 SAB meeting:

ACX V = ELASTINITE SHAFT
PE 600 BALLOON

Attached is a brief summary of the heart model session. The guiding catheter did not provide any support for either device. If you have any questions please feel free to contact me.
Evaluations completed by:
Geoff Hartzler, M.D.
Don Baim, M.D.
Richard Stack, M.D.

The ACX V catheter was compared to the COBRA in a head to head evaluation in a heart model at 37°C. 7Fr POWERBASE guide was used. Specific performance characteristics were rated on a scale of 1-5 with 5=exceptional, 4=very good, 3=good/adequate, 2=fair, and 1=inadequate.

	Dr. Hartzler		Dr. Baim		Dr. Stack	
Attribute	ACX V	Cobra	ACX V	Cobra	ACX V	Cobra
Guidewire movement	5	5	4	2	5	4
Access (Track)	5	5	4	4	5	4
Push Transmission	5	5	4+	4	5	4
Transition from stiff shaft to distal shaft	5	5	4	4	5	4
Distal transition	5	5	4	4	5	4
Overall impression	5	5	4	4	5	4

Overall Ranking:	Dr. Hartzler	Dr. Baim	Dr Stack
	Equal	Equal	1. ACX V 2. Cobra

Comments:

Dr. Hartzler- Guidewire movement is exquisite.
Distal tip is abrupt - Needs some work.

Dr. Baim - Less force required to advance catheter. Has excellent transmission of push.
Transition from stiff shaft to distal segment does not impact guide (Length ok)
Tip is poor. Much more like COBRA than SLEEK.

Dr. Stack- Excellent guidewire movement.
Was able to track around a loop in the heart model artery - Good transmission of push.
Transition from stiff shaft to distal segment fine. It does not impact the guiding catheter.

ACX V Test Protocol

Study Date:	March 13, 1994
Location:	Stouffer Concourse Hotel SAB Meeting (Shannon Room)
CR Coordinator:	Margo Zaugg
Study Participants:	Don Baim, M.D. Geoff Hartzler, M.D. William O'Neill, M.D. Cass Pinkerton, M.D. Richard Stack, M.D.
Test Device:	ACX V
Control Device:	Scimed Cobra
Objective:	Assess in-vitro performance against Cobra.
Key elements:	Guidewire movement Track Push Transition from stiff shaft to distal segment Transition / joint proximal to balloon Length of stiff shaft
Method:	The evaluation will be performed in a 37c water bath using a 7 Fr or 8 Fr JL4 ACS POWERGUIDE, .014" HTF DOC compatible guidewire, inflation device and PTCA accessories.
Scoring:	After the device has been used, each performance attribute will be given a score by the operator. 1 = inadequate 2 = fair 3 = good / adequate 4 = very good 5 = exceptional After both devices have been tested, the operator will rank the devices in order of preference.
Procedure:	* Position the 8 Fr JL4 POWERGUIDE in the LM coronary artery. * Track the Cobra catheter over the .014" HTF as far as possible into the anatomy of the heart model. (Note distance) * Remove Cobra without inflating. * Track the ACX V catheter over the .014" HTF as far as possible into the anatomy of the heart model. (Note distance) * Remove ACX V catheter without inflating.

ACX V Evaluation
March 13, 1994

Performance:

Guidewire movement:
Smoothness of wire movement within the catheter.
Smoothness of the balloon traveling over the wire.

Trackability
Overall ease with which the device travels through the anatomy.
Smoothness as the device goes around curves / tortuosity.

Transmission of push
Presence / absence of guiding catheter back out.
Presence / degree of dilatation catheter prolapse.
Distance the catheter travels within the anatomy.
Physician perception

Transition from stiff shaft to distal segment
Presence / absence of guiding catheter back out
Smoothness of guidewire movement within the catheter.
Feedback from visual inspection

Transition / Joint proximal to the balloon
Presence / absence of catheter prolapse
Feedback from visual inspection

FINAL STUDY REPORT

Animal study title: Next Platform .014" (OTW shaft evaluation)

Protocol number: next14p74.wp
final report number: nex14f74.wp
companion .xls spread sheet: nex14f74.xls
Laboratory notebook # (file #): LB# 1292, pgs 37-49

Study date(s): July 29, 1994

Test and control devices: Each investigator evaluated one of each of the following test devices, and one competitive control.

test:
1. 3.0 PEEK, co-axial proximal shaft, co-axial distal section. (# A1, # A5)

2. 3.0 PEEK, co-axial proximal shaft, elliptical distal section. (#C2, #C5)

3. 3.0 PE, continuous elliptical/dual lumen shaft. (#B1, #B4)

control:
1. 3.0 Sci-Med Cobra
2. 3.0 Sci-Med 14K

Study site: Mayo Clinic, Rochester Minnesota

Investigators: Dr. Kirk Garratt, Dr. Stuart Higano

ACS personnel: 1. engineer(s)/other participant(s):
Dan Cox, Eric Petersen, Colleen McQueen

2. IR study coordinator: Dan Meeker

Objectives and specific aims: The goal of the study is to identify the shaft design for the Next Platform .014" catheter. The following functional parameters were evaluated.

1. **guide wire movement**
2. **access to the lesion (combination of track and push)**
3. **cross (combination of push and profile).**

Study performance (ease of following protocol, difficulties encountered; see also detailed methods in attached protocol):

Two pigs and two investigators were used for the evaluation.

Each investigator evaluated one of each of the three test versions in comparison to one competitive control. Dr. Higano used a Sci-Med Cobra as a control and Dr. Garratt used a Sci-Med 14K as a control.

To more effectively evaluate the shaft designs a 7F guiding catheter was used in pig # 835 to reduce the amount of support supplied to the test and control catheters by the guiding catheter.

The RCA lesions for both pigs (835, 829) were approximately 10 cm from the tip of the guiding catheter and 95% in degree of stenosis. The tortuosity was 5/10 in degree of difficulty for both pigs.

Summary of results (also see attached data sheets for individual animal results):

Aim 1: Guide wire movement

Note: Guide wire movement was evaluated and rated with the guide wire advanced and positioned through the lesion. This may have impaired guide wire movement ratings in this study, although was considered a clinically relevant situation to evaluate guide wire movement.

The average guide wire movement rating for both investigators on all three versions of test catheters was 3.75. Dr. Garratt rated all test catheters 4.5 on guide wire movement. Dr. Higano rated all test catheters 3.0 on guide wire movement.

The guide wire movement rating for the Sci-Med Cobra for Dr. Higano's evaluation was 2.0.

The guide wire movement rating for the Sci-Med 14K for Dr. Garratt's evaluation was 4.0.

Aim 2: Access

All test and control catheters were rated between 4.0-4.5 on guide wire movement for both investigators.

Aim 3: cross

The average rating for co-axial/co-axial test catheters (#A1,#A5) was 4.25 in cross for both investigators.

The average rating for continuous elliptical test catheters (#B1,#B4) was 4.25 in cross for both investigators.

The rating for co-axial/elliptical (#C2) was 4.0 in cross. The rating for co-axial/elliptical (#C5) was 1.0 in cross.

The Sci-Med 14K evaluated by Dr. Garratt was rated 3.0 on cross.

The Sci-Med Cobra evaluated by Dr. Higano was rated 1.0 on cross.

Next Platform .014" (OTW) shaft evaluation				
Mayo Clinic animal studies, July 29, 1994				
Dr. Kirk Garratt, Dr. Stuart Higano				
Listed below are the catheters in the order they were evaluated .				
	gw mov	access	cross	comments
Garratt				
14K	4.0	4.5	3.0	crossed with deep seatinng
Garratt	4.5	4.5	4.0	guide bob w/ modest guide place
co-ax,elip (C2)				
Garratt	4.5	4.5	4.5	no guide move at all on modest
co-ax,co-ax (A1)				guide placement
Garratt	4.5	4.5	4.5	slt guide bob w/ modest guide
Contin, elip, (B1)				placement
Higano	2.0	4.0	1.0	could not cross
Cobra				with deep seating
Higano	3.0	4.0	1.0	could not cross with deep seating
co-ax,elip (C5)				but got 1 mm further than above
Higano	3.0	4.0	4.0	crossed w/ modest guide placement
co-ax,co-ax (A5)				no bob, steady push
Higano	3.0	4.0	4.0	crossed,same as above
contin, elip (B4)				

Post-study procedures (histology, shipping etc.):

All catheters have been properly re-packaged and returned to ACS for further analysis.

Comments and conclusions:

All test and control catheters evaluated by both investigators were considered similar in guide wire movement and access to the lesion. Neither guide wire movement nor access to the lesion was considered directly responsible for the overall outcome of the studies. This was due to the lack of tortuosity rated 5/10 in degree of difficulty in both animals.

The co-axial/co-axial and continuous/elliptical test catheters evaluated by both investigators performed significantly better in cross than the co-axial elliptical test catheters or either Sci-Med competitive control.

The co-axial/co-axial test catheters was regarded as slightly better in cross than the continuous elliptical test catheters although it is difficult to distinguish in this evaluation due to the increasing lumen size of the lesion with subsequent crosses. In both comparisons the continuous/elliptical designs followed the co-axial/co-axial designs.

In the first set both were rated 4.5 on cross with the continuous/elliptical design "bobbing" the guiding catheter as it crossed. The co-axial/co-axial design did not move the guide as it crossed the lesion.

In the second set the co-axial/co-axial test catheter advanced easily through the lesion after the co-axial/elliptical test catheter and Sci-Med Cobra failed to cross. The continuous/elliptical followed the co-axial/co-axial test catheter and was advanced through the lesion with similar effort as the co-axial/co-axial design.

It can not be determined whether the continuous/elliptical design would have crossed if it had been evaluated before the co-axial/co-axial design. The lumen diameter may have been increased by the co-axial/co-axial design prior to the continuous/elliptical evaluation.

SUMMARY:

In separate evaluations the performance of the co-axial\co-axial design was rated better than the co-axial\elliptical design and as good or better than the continuous elliptical design according to Dr. Garratt and Dr. Higano.

The three test versions performed better in cross in both evaluations than the Sci-Med Cobra or 14K competitive control catheters.

The animal study results are consistent with in-house heart modeling results.

Dr. Higano preferred the "sturdier", "stiffer" proximal shaft of the continuous/elliptical version, but indicated that the proximal shaft of the co-axial/co-axial design was a significant improvement over the proximal shaft of the Edge.

MEMORANDUM

Note:
Per D. Houlsby, New Platform requirements will be similar to those described for the VHP.
[signature] 8/23/94

Date: August 15, 1994

From: R.D. Houlsby

To: File

Subject: VHP Design Review

STERILIZATION

The sterilization mode will be **E-Beam**. Validation will be performed according to AAMI Method 1. The **dose setting** method requires that the **bioburden** be determined for 3 lots of 10 catheters, 30 total. The average bioburden is used to determines the **verification dose**. One-hundred catheters are exposed to the verification dose and tested for sterility. The verification dose is accepted if there are no more than two catheters positive for growth (unsterile). The acceptance of the verification dose is used to determine the **sterilization dose**. The sterilization dose is the dose that provides a sterility assurance factor of 10^{-6} (**SAL** = 10^{-6}), which means the failure rate is less than one in million. The sterilization dose that is determined from the verification dose is expected to be less than 25 kGy (2.5 MRad); however, ACS will sterilize all of its devices at 25 kGy even if the verification dose supports a lesser amount.

Sterilization validation is **site specific** because the bioburden in one geographical area may differ from the bioburden in another area. Thus, ACS should validate the dose for each manufacturing site. Validation of the Santa Clara manufacturing site will have to be done before submission to FDA. EDC validation will be based in part on previous validation studies and will only require one shipper carton of catheters to verify the dose map.

Dose mapping, the distribution of dose throughout the package, is necessary to complete sterilization validation. Dose mapping has been done on several polyethylene catheters both at IRT (San Diego) and at the EDC sterilizer in Europe. These dose maps can used to support the VHP catheter provided that the same packaging is used. Different packaging would require a new dose map (at least one shipper carton of 10 devices).

Quarterly audits will be required initially for at least the first year of production. These audits consist of repeating the verification dose using 100 catheters. The audits may become less frequent as ACS accumulates more data.

BIOCOMPATIBILITY

The **raw materials** used in the VHP catheter are given in the attached Bill of Materials. All of these materials, in one form or another, have been screened for biocompatibility using the test for cytotoxicity. Some materials have also been tested for hemolysis. These screening tests were mostly done on unsterilized materials. In addition, prototype devices containing all of the materials were tested for cytotoxicity and hemolysis after exposure to 50 kGy. The results of these tests indicate that the materials have a high probability of passing the biocompatibility tests required for finished goods.

The **finished good** biocompatibility tests have not been initiated at this time. The testing takes two months to complete. The tests included:

1. Cytotoxicity
2. Hemolysis
3. Class IV
    a. Intracutaneous Toxicity (Irritation)
    b. Acute Toxicity
    c. Implant
4. Ames (mutagenicity)
5. Sensitization
6. Sub-Chronic

The tests have to be done using devices sterilized by a validated cycle. These tests are described in SOP 22609C.

RD Houlsby
8-15-94

VHP DESIGN REVIEW

STERILIZATION

MODE: E-BEAM

VALIDATION REQUIREMENTS:

SDC: 30 CATHETERS FOR BIOBURDEN

100 CATHETERS FOR VERIFICATION DOSE

EDC: 1 SHIPPER CARTON

DOSE MAPPING: EXISTING DOSE MAPS CAN BE USED.

RD Houlsby
8-15-94

VHP DESIGN REVIEW

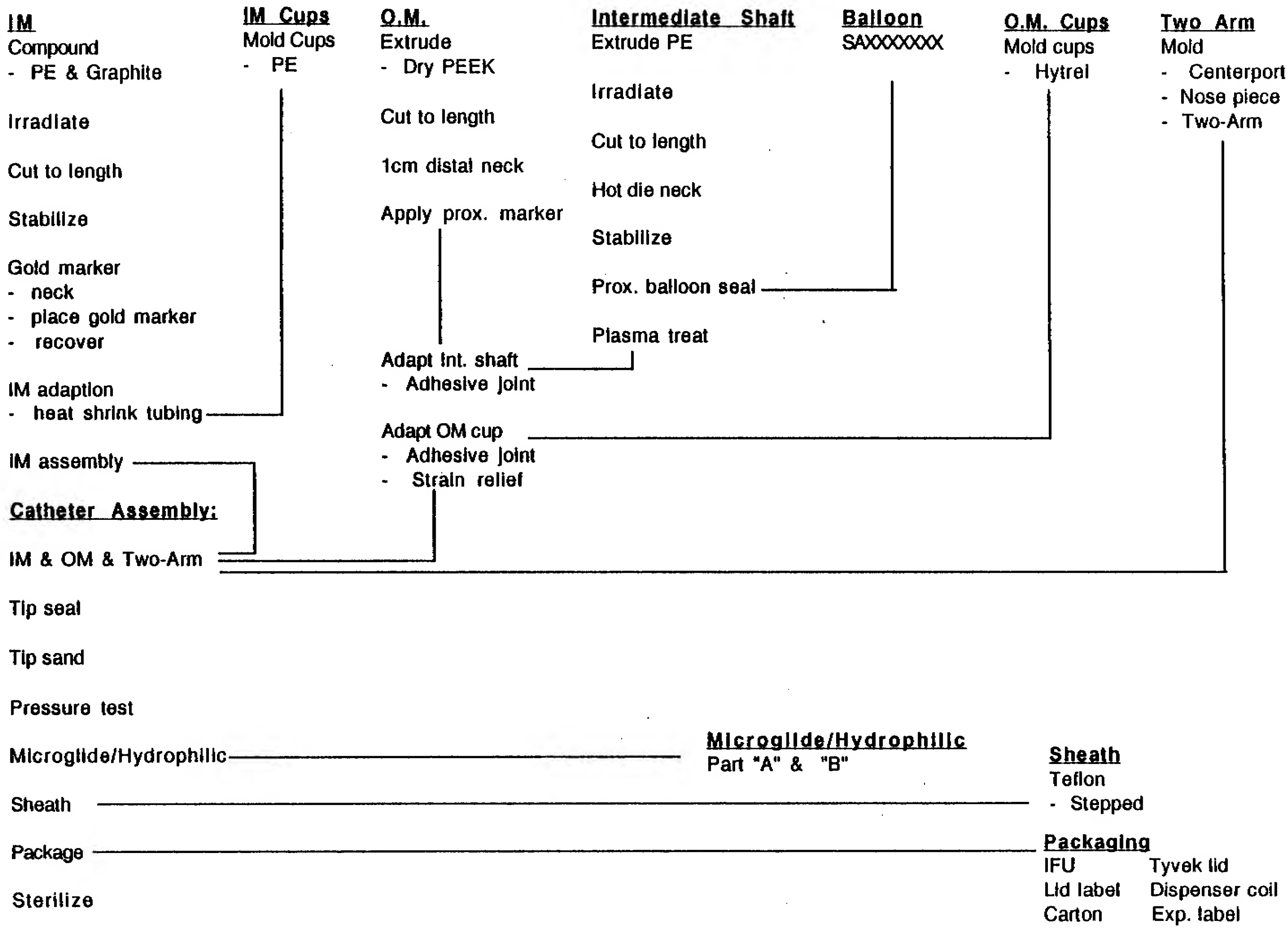
BIOCOMPATIBILITY

RAW MATERIALS: Qualified previously by tests for cytotoxicity, some hemolysis testing.

FINISHED GOODS: INCOMPLETE
2 MONTHS LEAD TIME
26 CATHETERS

- CYTOTOXICITY
- HEMOLYSIS
- CLASS IV
  - a. Intracutaneous tox.
  - b. Acute systemic tox.
  - c. Implant
- AMES (mutagenicity)
- SENSITIZATION
- SUB-CHRONIC

OTW COAXIAL DESIGN ASSEMBLY FLOWCHART



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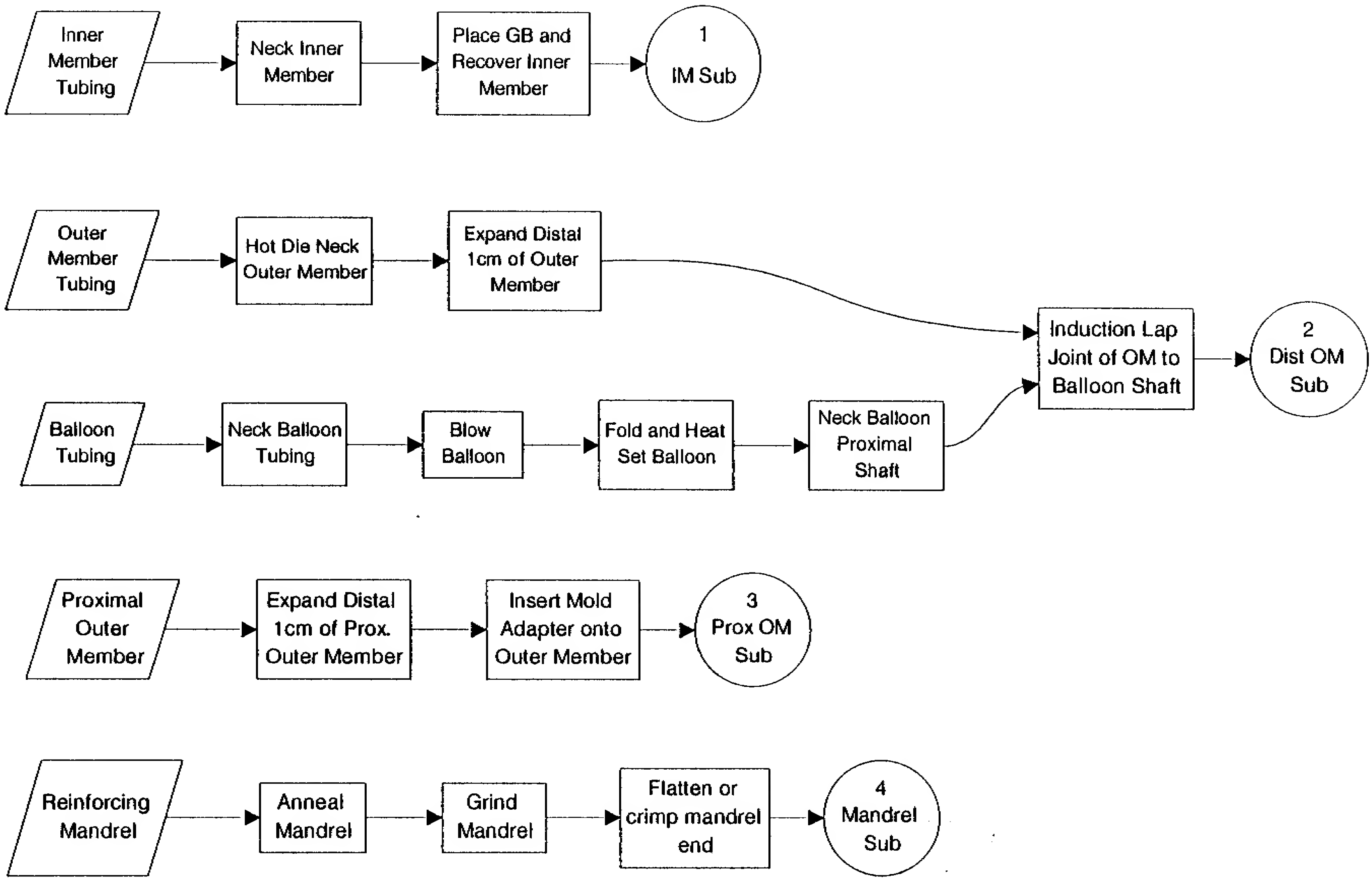
Eric Leopold
8/13/94

New Platform RX



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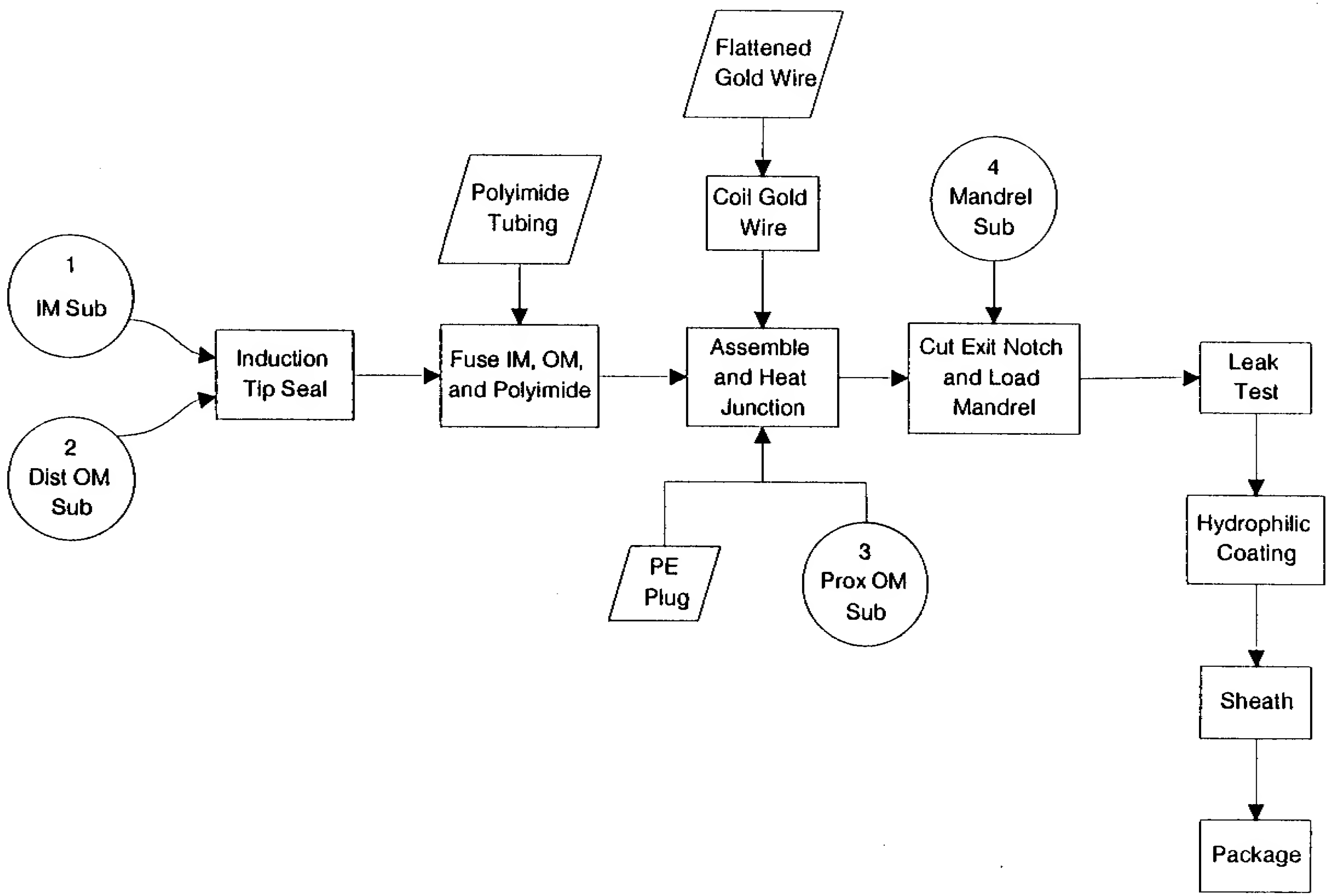
Eric Leopold
8/13/94

New Platform RX



Failure
Mode,
Effect, and
Criticality
Analysis

From: Victor Nguyen
Diem Ta
Date: August 22, 1994

Program: **New Platform .014 OTW/RX**

Subject: **FMECA**

1.0 **FMECA:** Failure Modes and Effects Criticality Analysis

2.0 Purpose and Goals of the FMECA:

Purpose:
1). To analyze the product design for safety, reliability and effectiveness.

Goal:
1). To identify any "Critical Components".
2). To analyze each component and establish a "Risk priority number" for each failure mode and take corrective action for each potential failure could have an adverse effect on the Mission, and final design specification and intent of this product.

3.0 **Approach:** To analyze each component and subassembly, where appropriate, with a "bottoms" up approach and identify the potential failure modes of that component or subassembly.

PRELIMINARY PRODUCT FMECA

PRODUCT: Distal Shaft of .014 New Platform Catheter (OTW & RX)
PROJECT ENGINEERS: Dan Cox, Eric Leopold, & Larry Wasicek

DATE: 8/18/94
REV.: A
PREPARED BY: Dan Cox, Eric Leopold, Victor Nguyen, Diem Ta, & Larry Wasicek

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
1	Tip	Provides a balloon seal and aids in catheter crossability.	1. Seal leaks.	1. Pressure loss 2. Difficult to deflate balloon.	Seal delaminates.	1. Measure seal length with ruler. 2. Visually inspect seal for completeness. 3. Leak test complete catheter to 150 psi, sheathed.	1	8	1	8
			2. Long	Poor trackability	Tip is cut longer than spec.	Measure tip length with ruler.	4	1	4	16
			3. Short taper	Poor crossability	Taper is cut shorter than spec after sanding.	Measure taper length with ruler.	4	5	4	80
			4. Shallow taper angle	Poor crossability	Tip is improperly sanded.	Measure taper length with ruler.	3	5	4	60
			5. Large OD	Poor crossability	Tip seal process is inconsistent.	Measure tip OD with hole gauge.	2	5	2	20

PRODUCT: Distal Shaft of .014 New Platform Catheter (OTW & RX)
PROJECT ENGINEERS: Dan Cox, Eric Leopold, & Larry Wasicek

DATE: 8/18/94
REV.: A
PREPARED BY: Dan Cox, Eric Leopold, Victor Nguyen, Diem Ta, & Larry Wasicek
Page 2 of 5

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
2	Balloon	Dilates lesion when inflated.	1. Micro tear at end of distal taper	1. Pressure loss 2. Jet stream of contrast medium perforates arterial wall. 3. Difficult to deflate balloon.	Heat damage to distal taper from tip seal process	Leak test complete catheter to 90 psi, unsheathed.	1	9	3	27
			2. Pinholes.	1. Pressure loss 2. Jet stream of contrast medium perforates arterial wall. 3. Difficult to deflate balloon.	1. Mechanical damage 2. Flaw in balloon material	1. On-line rupture test of balloon subs 2. Leak test complete catheter to 90 psi, unsheathed.	2	9	3	54
			3. Radial rupture	1. Pressure loss 2. Dissection	1. Mechanical damage 2. Flaw in balloon material	1. On-line rupture test of balloon subs 2. Leak test complete catheter to 90 psi, unsheathed.	1	9	3	27
			4. Circumferential rupture	1. Pressure loss 2. Dissection 3. Balloon entrapment 4. Embolization of any detached balloon material	1. Mechanical damage 2. Flaw in balloon material	1. On-line rupture test of balloon subs 2. Leak test complete catheter to 90 psi, unsheathed.	1	9	3	27
			5. Longitudinal rupture below RBP	1. Pressure loss 2. Dissection	1. Mechanical damage 2. Flaw in balloon material 3. Overpressurization	1. On-line rupture test of balloon subs 2. Leak test complete catheter to 90 psi, unsheathed.	2	8	3	48
			6. Poor fold in distal taper and/or balloon	Poor crossability	Balloon is poorly folded in balloon folding process.	Visually inspect balloon fold after folding for wrinkles.	2	5	3	30
			7. Large OD	Dilated artery is stretched.	1. Wrong sized balloon 2. OD is out of spec.	Measure balloon OD at 90 psi with snap gauge.	2	7	2	28

PRODUCT: Distal Shaft of .014 New Platform Catheter (OTW & RX)
PROJECT ENGINEERS: Dan Cox, Eric Leopold, & Larry Wasicek

DATE: 8/18/94
REV.: A
PREPARED BY: Dan Cox, Eric Leopold, Victor Nguyen, Diem Ta, & Larry Wasicek

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
3	Proximal balloon seal	Provides a transition from one outer member material to another.	1. Leaks.	1. Pressure loss 2. Difficult to deflate balloon if leak is significant. 3. Separation of junction for complete delamination	Seal delaminates.	1. Measure seal length with ruler. 2. Visually inspect seal for completeness. 3. Leak test complete catheter to 150 psi, sheathed.	1	8	2	16
			2. Pinholes.	1. Pressure loss 2. Jet stream of contrast medium perforates arterial wall. 3. Difficult to deflate balloon.	Mechanical damage	Leak test complete catheter to 150 psi, sheathed.	1	9	9	81
			3. Large OD	Poor trackability	Wrong sized sheath is used for seal formation.	Measure seal OD with snap gauge.	3	2	1	6
			4. Long	Poor trackability	Operator error	Measure seal length with ruler.	3	2	1	6
4	Distal shaft outer member	Provides an inflation/deflation lumen.	1. Kinks.	1. Long deflation time 2. Poor trackability and pushability	Handling	Visually inspect shaft for kinks throughout manufacturing.	4	5	7	140
			2. Large OD	1. Poor trackability 2. Poor visualization	Improper necking	Measure OD with snap gauge.	2	2	1	4
			3. Small ID	Long deflation time	Extrusion	1. ID is measured in receiving inspection. 2. Size of mandrel used for necking process	2	4	1	8
			4. Ruptures.	1. Pressure loss 2. Dissection	1. Mechanical damage 2. Flaw in extrusion	1. Visual inspection of tubing for anamolies in receiving inspection. 2. Leak test complete catheter to 150 psi, sheathed.	4	9	10	360

PRODUCT: Distal Shaft of .014 New Platform Catheter (OTW & RX)
PROJECT ENGINEERS: Dan Cox, Eric Leopold, & Larry Wasicek

DATE: 8/18/94
REV.: A
PREPARED BY: Dan Cox, Eric Leopold, Victor Nguyen, Diem Ta, & Larry Wasicek

ID #	COMPONENT	FUNCTION	POTENTIAL* FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION: CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
5	Distal shaft Inner member	Provides a guide wire lumen.	1. Large OD	Long deflation time	Extrusion	OD is measured in receiving inspection.	1	4	4	16
			2. OD under balloon is large.	Large 2/3 balloon profile	Balloon marker recovering process is improper.	Measure OD with snap gauge after recovering process.	2	3	4	24
			3. Small ID	1. Poor guide wire movement 2. Poor distal flow rate (OTW only)	Extrusion	1. ID is measured in receiving inspection. 2. Size of mandrel used to keep lumen open during manufacturing 3. Inspect guide wire movement.	2	5	2	20
			4. Kinks.	1. Poor guide wire movement 2. Poor trackability and pushability 3. Poor distal flow rate (OTW only)	1. Handling 2. Thin wall	Wall thickness of tubing is measured in receiving inspection.	2	5	7	70
			5. Collapses during balloon inflation.	1. Guide wire movement restricted. 2. No distal flow (OTW only)	Thin wall	1. Wall thickness of tubing is measured in receiving inspection. 2. Size of mandrel used to keep lumen open during manufacturing 3. Measure OD with snap guage. 4. Leak test complete catheter to 150 psi. sheathed.	2	5	4	40
			6. Pinholes.	1. Pressure loss 2. Difficult to deflate balloon.	1. Flaw in extrusion 2. Mechanical damage	1. Visual inspection of tubing for anamolies in receiving inspection 2. Leak test complete catheter to 150 psi. sheathed.	3	7	3	63

PRELIMINARY PRODUCT FMECA

PRODUCT: Distal Shaft of .014 New Platform Catheter (OTW & RX)
PROJECT ENGINEERS: Dan Cox, Eric Leopold, & Larry Wasicek

DATE: 8/18/94
REV.: A
PREPARED BY: Dan Cox, Eric Leopold, Victor Nguyen, Diem Ta, & Larry Wasicek

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
6	Balloon marker	Aids physician in positioning balloon in lesion.	1. Not centered in balloon.	Misposition balloon in lesion. Consequently, dilate good artery.	Operator error	Measure marker location with ruler.	1	3	1	3
			2. Has rough edges.	Mechanical damage to inside surface of balloon	1. Burrs on marker from vendor 2. Balloon marker recovering process is improper.	1. Visual inspection of marker for rough edges in receiving inspection 2. Visually inspect marker for rough edges after recovering process.	2	4	2	16

PRELIMINARY PRODUCT FMECA

PRODUCT: Proximal Shaft of RX .014 New Platform Catheter
PROJECT ENGINEERS: Eric Leopold

DATE: 8/22/94
REV.: A
PREPARED BY: Eric Leopold & Diem Ta

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
1	Reinforcing mandrel	Provides catheter pushability.	1. Distal end of mandrel pokes through distal shaft outer member.	1. Pressure loss 2. Distal end of mandrel perforates arterial wall. 3. Distal end of mandrel damages artery upon catheter removal from patient.	Balloon entrapment upon catheter removal from patient causes distal end of mandrel to poke through distal shaft outer member.	Ensure distal end of mandrel is rounded.	1	9	9	81
			2. Dislodges from proximal adaption and comes out of proximal adaptor.	Lose pushability.	Poor bond at proximal adaption	Visually inspect mandrel engagement in proximal adaption.	2	3	2	12
			3. Large diameter	Long deflation time	1. Out-of-spec part from vendor 2. Improper grinding of mandrel	1. Receiving inspection measures diameter of mandrel received from vendor with calliper. 2. Receiving inspection measures mandrel diameter with calliper after grinding.	2	4	1	8
			4. Bends.	Poor trackability and pushability	Handling	Visually inspect mandrel on line for bends.	2	3	7	42
			5. Diameter of mandrel in polyimide is large.	Long deflation time	1. Improper taper length 2. Improper mandrel placement	1. Receiving inspection measures mandrel diameter with calliper after grinding. 2. Measure location of distal end of mandrel with ruler.	2	4	3	24
			6. Sharp distal end	Distal end of mandrel damages distal shaft outer member.	Improper sanding of distal end	Receiving inspection inspects distal end of mandrel for roundness.	3	9	3	54

RXPSHFME.XLS

PRELIMINARY PRODUCT FMECA

PRODUCT: Proximal Shaft of RX .014 New Platform Catheter
PROJECT ENGINEERS: Eric Leopold

DATE: 8/22/94
REV.: A
PREPARED BY: Eric Leopold & Diem Ta

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
2	Mid-catheter junction	Provides transition in catheter pushability and guide wire exit.	1. Kinks.	1. Long deflation time 2. Poor guide wire movement 3. Difficult for guide wire to exit. 4. Poor trackability and pushability	Handling	Visually inspect junction for kinks and check guide wire exit.	2	4	7	56
			2. Leaks.	1. Pressure loss 2. Difficult to deflate balloon. 3. Separation for complete delamination	1. Seal delaminates. 2. Gold coil damages proximal shaft outer member.	1. Visually inspect junction for discrepancies. 2. Leak test complete catheter to 150 psi, sheathed.	2	8	3	48
			3. Distal end of polyimide blocked	1. Long deflation time for partial blocking 2. Unable to inflate or deflate balloon for complete blocking.	Distal shaft outer member is fused over distal end of polyimide.	Measure location of distal end of polyimide relative to taper of distal shaft outer member with ruler.	2	4	2	16
			4. Large OD	Poor visualization	Junction forming process is inconsistent.	Measure junction OD with snap gauge.	2	4	2	16

RXPSHFME.XLS

PRELIMINARY PRODUCT FMECA

PRODUCT: Proximal Shaft of RX .014 New Platform Catheter
PROJECT ENGINEERS: Eric Leopold

DATE: 8/22/94
REV.: A
PREPARED BY: Eric Leopold & Diem Ta

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCC.	SEV.	DET.	RISK PRIORI. # (RPN)
3	Proximal shaft outer member	Provides an inflation/deflation lumen.	1. Kinks.	1. Long deflation time 2. Poor trackablity and pushability	Handling	Visually inspect shaft for kinks throughout manufacturing.	4	5	7	140
			2. Large OD	1. Poor trackablity 2. Poor visualization	Extrusion	Receiving inspection measures OD with snap gauge.	2	2	1	4
			3. Small ID	Long deflation time	Extrusion	Receiving inspection measures ID.	2	4	1	8
			4. Ruptures.	1. Pressure loss 2. Dissection	1. Mechanical damage 2. Flaw in extrusion	1. Receiving inspection visually inspects tubing for anamolies. 2. Leak test complete catheter to 150 psi, sheathed.	2	7	10	140
4	Proximal adaption/ proximal adaptor	Provides an inflation/deflation port.	1. Leaks.	1. Pressure loss 2. Difficult to deflate balloon.	Improper shrinkage of adaption cup and/or shrink tubings	Leak test complete catheter to 150 psi, sheathed.	2	8	3	48
			2. Separates from proximal shaft.	No inflation/deflation	Improper shrinkage of adaption cup and/or shrink tubings	1. Visually inspect proximal adaption for discrepancies after shrinkage of adaption cup and shrink tubings. 2. Leak test complete catheter to 150 psi, sheathed.	1	9	10	90
			3. Cracked port	1. Pressure loss 2. Difficult to deflate balloon.	Overtightening of proximal adaptor port in luer	1. Visually inspect proximal adaptor port for cracks. 2. Leak test complete catheter to 150 psi, sheathed.	1	8	2	16

RXPSHFME.XLS

PRELIMINARY PRODUCT FMECA

PRODUCT: Proximal shaft of .014 New Platform Catheter (OTW)
PROJECT ENGINEERS: Dan Cox, , Larry Wasicek
PREPARED BY: Victor Nguyen
Larry Wasicek

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCCURENCE	SEVERITY	DETECTION	RISK PRIORITY # (RPN)
1	center port	RHV & GW port	1. no thread	no connection	molding error	RI inspection	1	1	1	1
			2. no seal	leaks	operator error		1	2	1	2
			3. excessive flash	contamination in bloodstream	molding error		1	2	2	4
2	nosepiece	mechanical lock to seat	1. no thread	leaks	molding error	RI inspection	1	1	1	1
			2. no dichlormethane	won't seal	operator error	pressure test on line	1	1	1	1
3	two arms	inflation/deflation connection place for label	1. cracked	leaks	pressure drop	RI inspection visual insp. on line	2	3	2	12
			2. excessive flash	contamination in bloodstream	molding error		2	2	2	8
4	dichlormethane	lock nosepiece and centerport in place	1. defective mat'l (ie: impure)	leaks	operator error	RI check for supplier cert.	2	1	4	8
5	adhesive 350	seal lap joint	1. separation of prox. shaft and intermediate shaft	pressure drop	expired adhesive	RI check for supplier cert.	2	1	4	8
6	proximal markers	catheter location	1. advance too far	damage vessel	improper marker location	check length and location on line	1	3	2	6

PRELIMINARY PRODUCT FMECA

PRODUCT: Proximal shaft of .014 New Platform Catheter (OTW)
PROJECT ENGINEERS: Dan Cox, , Larry Wasicek
PREPARED BY: Victor Nguyen
Larry Wasicek

ID #	COMPONENT	FUNCTION	POTENTIAL FAILURE MODE(S)	POTENTIAL EFFECT(S) OF FAILURE	CAUSE(S) OF FAILURE	EXSISTING CONDITION				
						CURRENT CONTROL	OCCURENCE	SEVERITY	DETECTION	RISK PRIORITY # (RPN)
7	lap joint	aid in forming junction with stiff shaft and intermediate shaft Pushability	1. split	separation of distal end and prox. shaft	soft mat'l	visual check for length, OD on line	2	9	2	36
			2. leaks	pressure drop	seal delaminates old adhesive		2	8	2	32
			3. big OD	reduce contrast die injection	operator error		3	3	2	18
			4. long length	lack of transmission of track			2	3	2	12
8	strain relief tubing	prevent kinking	1. kink	no inflation/deflation	operator error	RI inspection	1	4	4	16
9	inner member adaptor cup	adapt IM shaft to two arms	1. thin wall	leaks due to split , crack or broken adaptor cup	molding error	RI inspection	1	2	6	12
			2. excessive flash	leaks			2	4	3	24
			3. different or inferior mat'l	won't bond, leaks			1	5	2	10
10	outer member adaptor cup	adapt prox. shaft to two arms	1. large shaft ID	leaks	molding error	RI inspection	3	4	2	24
			2. thin wall	leaks due to split			1	2	6	12
			3. excessive flash	leaks			2	4	3	24
			4. different or inferior mat'l	won't bond, leaks			1	5	2	10
11	proximal shaft outer member	provides an inflation/deflation lumen	1. kinks	long deflation time	handling	RI inspection	4	5	7	140
			2. large OD	poor trackability	extrusion		2	4	1	8
			3. small ID	long deflation time			2	5	1	10
			4. ruptures	pressure drop			4	7	10	280
12	proximal shaft inner member	provides a GW lumen	1. large OD	long deflation time	extrusion	RI inspection	2	4	2	16
			2. small ID	poor GW movement			2	5	1	10
			3. kinks	poor GW movement poor trackability and pushability	handling		3	5	7	105
			4. pin holes	pressure drop	flaws in extrusion		2	7	9	126

FMEA2.XLS

6.0 <u>Occurrence:</u> Is the likelihood that a specific cause will result in a specific failure mode. Take into consideration that the control is in place and is successful. Apply a rating scale of (1-10) with (10) being the most likely to occur. Use the Qualitative Approach for probability of failure as follows:

Ranking	Probability of Failure
1	Remote: Fairly Unlikely
2,3	Low: Relatively few
4,5,6	Moderate: Occasional
7,8	High: Repeated Failures
9,10	Extreme: Almost Inevitable

7.0 <u>Severity:</u> is an assessment of the failure effects on the local area, next level areas, and the end user. The Severity rating applies to the effects.

Evaluation Criteria:

Ranking	Qualitative Approach (Degree of Severity)
1	Improbable, Minor: Failure will not have a perceptible effect on the performance of the product. The user or patient will not notice the failure or be harmed.
2,3	Insignificant, Low: User is only minimally affected. - user will only notice a minor nuisance or negative impact on the product and there is no harm to the user or the patient. - Nuisance item, product will be operable at reduced performance.
4,5,6	Moderately Significant: Failure causes dissatisfaction on the part of the user. Noticeable negative impact on the product or system performance. Product operable at reduced performance and possible performance degradation. No harm to user or patient.
7,8	Significantly High: Failure causes greater annoyance to the user. Loss of product function but very low probability of harm to the patient or user.
9	Extremely Significant/ Very High: Loss of system function. Possible injury to user or patient. Not out of compliance with legal requirements.
10	Catastrophic: Severe health risk to user or patient. Involves non-compliance with government regulations.

8.0 Detection: is an assessment of the existing/proposed controls to identify any potential failure mode prior to occurrence. Rating the probability of detection is based on the effectiveness of the existing/proposed control system throughout the design or manufacturing cycle. To receive a better rating either the existing/proposed control system must be improved, or the design must be revised to improve the effectiveness of the current control.

Ranking	Qualitative Approach Probability of Detection
1	Will be detected prior to release for production.
2,3	Very likely will be detected prior to final release to production or shipping.
4,5,6	May be detected prior to production or shipping.
7,8	May not detect a potential design problem, however the failure mode will be detected prior to actual use.
9,10	Undetectable until failure occurs in use.